COMMENT

THE EXPERIMENTAL USE EXCEPTION TO INFRINGEMENT APPLIED TO FEDERALLY FUNDED INVENTIONS

SUZANNE T. MICHEL †

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I. INTRODUCTION

With one minor exception[1] the patent statutes do not suggest any instance in which use of a patented invention is not infringement. According to 35 U.S.C. § 154, "[e]very patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using or

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† J.D. candidate 1993, School of Law (Boalt Hall), University of California at Berkeley; Ph.D. 1989, Yale University; B.S. 1984, Northwestern University.

1. 35 U.S.C. § 271(e) provides that it is not an act of infringement to make, use, or sell a patented invention for purposes reasonably related to obtaining FDA approval of drugs.

selling the invention throughout the United States." Section 271(a) provides that "whoever without authority makes, uses or sells any patented invention . . . infringes the patent."

In spite of the seemingly unyielding dictate of the statutes, courts have recognized experimental use as an exception to infringement. Use of a patented invention "for the mere purpose of philosophical experimentation, or to ascertain the verity and exactness of the specification" is exempt from infringement.[2] While it is well settled that a patented invention may be made and used to test the verity and exactness of the specification, the scope of the "philosophical experimentation" prong of the exception is much less clear. The Federal Circuit has called this prong "truly narrow."[3] To be deemed philosophical experimentation, the experiment must be "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[4] The exception does not "allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable and not insubstantial commercial purposes."[5] Part II of this Comment describes the history and current scope of the experimental use exception.

In view of this narrow interpretation of the "philosophical experiment" prong of the experimental use exception, several commentators have called for a legislative broadening of the exception to encompass all activity short of commercialization.[6] A House bill, the Research, Experimentation and Competitiveness Act of 1990, also proposed broadening the exception.[7]

Those proposing the broad exception point to two key problems which they contend the broad exception would either clarify or solve. First, it is unclear whether university and other non-profit research done under contract with industry or with a purpose to patent the results is "strictly for philosophical inquiry." The uncertain limits of the doctrine might chill research or lead to litigation. Second, when a patent owner controls important information, that control might prevent a subsequent researcher from building on the information in a way that benefits society. The broad exception would allow subsequent research on patented inventions and would clarify the position of non-profit

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2. Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

3. Roche Prods., Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 863 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

4. *Id.*

5. *Id.*

6. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Ned A. Israelsen, *Making, Using, Selling Without Infringing: An examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AM. INTELL. PROP. L. ASS'N Q.J. 457 (1989).

7. H.R. 5598, 101st Cong., 1st Sess. §§ 401-403 (1990).

researchers. Part III describes the conditions which caused these two problems.

The task at hand is to find the wisest limits for the exception while providing a workable solution to the problems of foreclosed research and the uncertain position of non-profit researchers. Any proposal must take into account the economics and incentives of the patent system. Part IV critiques the wisdom of the proposals for a generally applicable broad exception. Part IV also argues that a generally applicable broad experimental use exception weakens the incentives to invent, to develop and to disclose provided by the patent system to too great an extent when applied to patents resulting from private research efforts.

Instead, this Comment proposes in Part V that the experimental use exception (extending up to commercialization) be made applicable only in the special circumstances in which its harm to patent incentives is minimal compared to the resulting benefits. First, university and other non-profit researchers should be allowed the advantage of the broad exception. This first proposal clarifies the position of non-profit researchers with minimal harm to the patent holder. Second, any party should be allowed to use a patented, federally funded invention in research and development. This second proposal provides a number of benefits without the disincentives which result when a broad experimental use exception is applied to privately funded patents. For instance, federally funded inventions will not foreclose subsequent research, but federal grantees will not lose their incentive to invent and disclose because those incentives come from outside the patent system.

II. BACKGROUND OF EXPERIMENTAL USE EXCEPTION

Understanding how the critique and proposals presented by this Comment fit into the framework of the patent laws first requires understanding the judicially created experimental use exception.

A. Creation and Early Development

The experimental use doctrine as a defense to patent infringement originated in 1813 in *Whittemore v. Cutter*, an opinion written by Justice Story while sitting on the Massachusetts Circuit Court.[8] The defendant in that case challenged a jury instruction that "the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right."[9] Justice Story approved the instruction on the grounds that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiment, or

8. Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).
9. *Id.* at 1121.

for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[10]

Justice Story referred to this exception again in *Sawin v. Guild*.[11] In holding that the defendant's use of patented machines constituted patent infringement, he noted that the machines had been used for profit rather than "for the mere purpose of philosophical experimentation, or to ascertain the verity and exactness of the specification. . . . In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery."[12] Even though experimental use was not an issue in either case, meaning that the exception originated in dicta, by 1861 the law on this subject was deemed "well-settled."[13]

Very few early cases applied the experimental use doctrine created by Justice Story to excuse use of a patented invention that would otherwise constitute infringement.[14] Even so, the second prong of Justice Story's test which allows activity for "ascertaining the verity and exactness of the specification" does appear to be "well settled." A party may wish to challenge a patent as invalid for not being enabling or useful and therefore must use the invention without a license to assemble proof of this invalidity. A party may also wish to test a patent before taking a license. Although there is little case law on the point, most commentators agree that this sort of activity is and should be protected by the exception.[15]

The scope of the "philosophical experiment" prong is much less clear. The cases that applied this prong simply concluded that the use in question was "experimental" without offering an elaboration of that term.[16] The commercial character of a use or the commercial intent of a user usually forfeited the protection of the doctrine in other early cases.[17] Overall, these early cases provide little guidance in setting the contours of the exception today.

Two more recent cases developed the "philosophical experiment" prong more fully, but neither found the doctrine to be applicable. In *Pitcairn v. United States*, the Court of Claims considered whether

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10. *Id.*

11. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

12. *Id.* at 555 (citation omitted) (citing *Whittemore*).

13. Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

14. The history of the experimental use exception from its creation to its application by the Federal Circuit is described elsewhere. *See* Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PA T. & TRADEMARK OFF. SO C'Y 617 (1985). Accordingly, this Comment presents only a summary.

15. Eisenberg, *supra* note 6, at 1074.

16. *See* Israelsen, *supra* note 6, at 460 n.11.

17. *See id.* at 460 n.14.

helicopters produced under contract for the United States infringed patents that had been previously declared valid by that court.[18] The court rejected the government's argument that the helicopters were purchased for testing and experimental purposes and therefore did not infringe.[19] The court held that "[t]ests, demonstrations and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency."[20] The helicopters were not built solely for experimental purposes and thus were excluded from the exception.

In *Pfizer, Inc. v. International Rectifier Corp.*, a federal district court held International Rectifier (IR) in contempt of court for violating an injunction which ordered IR to cease manufacture, use and sales of doxycycline, a pharmaceutical compound patented by Pfizer.[21] In spite of the injunction, IR had continued to manufacture doxycycline in order to conduct various tests such as bioequivalency and serum level tests.[22] IR also shipped doxycycline to laboratories in and out of the United States accompanied by a notice that the compound constituted laboratory samples for experimental purposes only.[23]

IR defended its activities on the grounds that they were solely experimental, and that the compound was never sold in the United States after the injunction. The court held these arguments to be "utterly without merit."[24] The court interpreted the history of the experimental use doctrine to suggest that "the underlying rule of permissible experimental use demands there must be no intended commercial use of the patented article, none whatsoever, if the exception is to be recognized at all."[25] Because IR's activities were for the purpose of competing with Pfizer after its patent expired, the court held IR in contempt. In addition, the court ordered IR to destroy all the doxycycline it possessed as well as all data it illicitly acquired regarding doxycycline.[26]

Both *Pitcairn* and *Pfizer* make clear that when a use is consistent with the "legitimate business" of the infringer or has an ultimate commercial purpose, the use is not "philosophical experimentation" and falls outside of the exception.

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18. Pitcairn v. United States, 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978).
19. *Id.* at 1124-25.
20. *Id.* at 1125-26.
21. Pfizer, Inc. v. International Rectifier Corp., 217 U.S.P.Q. (BNA) 157 (C.D. Cal. 1982).
22. These tests are required for FDA approval of generic drugs.
23. *Id.* at 158-59.
24. *Id.* at 160.
25. *Id.* at 161.
26. *Id.* at 163.

B. The Federal Circuit

In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the only Federal Circuit[27] case discussing at length the scope of the experimental use doctrine, the court interpreted the doctrine narrowly.[28] Bolar had imported five kilograms of Roche's patented compound flurazepam hydrochloride which Roche sold as a sleeping pill, Dalmane. Bolar used the compound to conduct the bioequivalency studies required for FDA approval with an eye toward marketing a generic version of the drug when Roche's patent expired a year later. Roche argued that this use constituted infringement, but the district court held that the use of a patented drug for testing related to FDA drug approval during the last six months of the patent term was *de minimis*, experimental and noninfringing.[29]

The Federal Circuit reversed, calling the experimental use exception "truly narrow."[30] The court's analysis first addressed the statute, noting that "[s]ection 271(a) prohibits, on its face, any and all uses of a patented invention," but admitted that the definition of "use" is a matter of judicial interpretation. The court cited *Pitcairn* for both the proposition that experimental use may be a defense to infringement and as setting forth the controlling law.[31] The court quoted *Pitcarin*'s statement that "'[t]ests, demonstrations, and experiments . . . [which] are in keeping with the legitimate business of the . . . [alleged infringer]' are infringements for which '[e]xperimental use is not a defense.'"[32]

Bolar did not come within the exception because its use was "not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[33] The court explained:

> [U]nlicensed experiments conducted with a view to adaption of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention. . . . We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable and not insubstantial commercial purposes.[34]

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27. The Federal Circuit, established in 1982, has jurisdiction over all appeals in cases "arising under" the federal patent laws. 28 U.S.C. § 1295 (1988).

28. Roche Prods., Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

29. Roche Prods., Inc. v. Bolar Pharmaceutical Co., 572 F. Supp. 255 (E.D.N.Y. 1983), *rev'd*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

30. *Roche*, 733 F.2d at 863.

31. *Id.* at 861, 863.

32. *Id.* at 863 (quoting Pitcairn v. United States, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978)).

33. *Id.*

34. *Id.*

Nor did the court consider the use *de minimis* even though the quantity used was small, because the testing could have had a significant economic impact on Roche if Bolar released the generic drug on the market earlier than it would have absent the infringement.[35]

1. *THE OVERRULING OF* ROCHE V. BOLAR

Shortly after the *Roche v. Bolar* decision, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984[36] which legislatively overruled that decision. That law exempts from infringement activity which is "reasonably related" to seeking FDA approval for a generic drug. The portion of the bill codified as 35 U.S.C. § 271(e)(1) states that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for purposes reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs."

The scope of the exemption is fairly narrow. The legislative history indicates that only a limited amount of testing to establish the bioequivalency of a generic drug substitute is permitted.[37] Whether an activity is "reasonably related" to seeking FDA approval has been narrowly interpreted in the case law.[38]

The legislation is interesting because it demonstrates a Congressional attitude which is willing to allow exceptions to infringement under some circumstances. The committee report states that the exemption did not substantially interfere with the rights of the patent holder because "[t]he patent holder retains the right to exclude others from commercial markets during the life of the patent."[39] In spite of this statement, Congress concurrently enacted a law which extended the patent grant for human drugs and other products which must undergo federal approval before marketing to compensate patentees for the time lost in which they can monopolize the market.[40] Patent owners essentially receive an extension of the patent term in exchange for their toleration of infringing use which enables a competitor to market a product as soon as the pertinent patent expires. This trade-off implies

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35. *Id.* at 866.

36. 35 U.S.C. § 271(e) (1988).

37. H.R. REP. NO. 857 pt. 2, 98th Cong., 2d Sess. 8 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2692.

38. Scripps Clinic v. Genentech, Inc., 666 F. Supp. 1379, 1396 (N.D. Cal. 1987) (a multiple purpose use of a patented invention is not exempted where only one purpose is reasonably related to FDA testing). However, the Supreme Court's decision in *Eli Lilly v. Medtronics* affirms a Federal Circuit decision to extend the scope of 271(e) to include the testing of medical devices. 872 F.2d 402 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

39. H.R. REP. NO. 857 pt. 2, *supra* note 37, at 8, *reprinted in* 1984 U.S.C.C.A.N. at 2692.

40. *Id.* at 14, *reprinted in* 1984 U.S.C.C.A.N. at 2691; 35 U.S.C. § 156 (1988).

that Congress may have conflicting views as to whether the harm to the patentee caused by the exempted experimental testing is as insubstantial as the legislative history suggests. The nature of an experimental use exception's interference with the patent right is discussed below in Section IV.C.

III. PROBLEMS WITH COMMON LAW DOCTRINE

Although the holding of *Roche* was overruled through legislation, that case is illustrative of the Federal Circuit's attitude toward the experimental use exception as a defense to infringement. The rationale of *Roche* remains the common law of experimental use in contexts other than the limited conditions of section 271(e). Given the narrow limits which that case places on the doctrine, any activity with a long-range profit motive or with any profit potential is unlikely to fall within the exception. Corporate research will nearly always be "in keeping with the legitimate business of the alleged infringer."

This narrow interpretation of the "philosophical experiment" prong of the experimental use exception engenders two related problems. First, it is unclear whether university research done under contract with industry or with a purpose to patent the results is "strictly for philosophical inquiry." Second, when a patent owner controls important information, that control might prevent a subsequent researcher from building on the information in a way that benefits society. The uncertain limits of the doctrine might chill research or lead to unnecessary litigation.

A. Uncertainty for Universities and Federal Laboratories

The extent to which use of a patented invention is permissible noninfringing experimentation when conducted by nonprofit researchers such as universities and federal labs remains unclear. Only one 1935 case, *Ruth v. Stearns-Roger Manufacturing Co.*, has addressed the issue of whether university use can be infringement. The district court in that case held that use of an infringing machine by the Colorado School of Mines was experimental and exempt from infringement because the machines were used in a laboratory and were cut up and changed from day to day. The school used the machines in furtherance of its educational purpose.[41]

Whether all research conducted in universities and federal laboratories today can be categorized as "philosophical experiments" is extremely problematic given the Federal Circuit's narrow interpretation

41. Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697, 703 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).

of that term. To understand how university research, which would appear to epitomize "philosophical experimentation," could fall outside the exception, we must examine the trend toward patenting and licensing university research and the relationships universities have forged with industry. It is through the universities' own attempts to monopolize research results and collaborate with the commercial sector that they have potentially lost claim to the experimental use exception. Part I through Part III below describe the current landscape of industry-university, industry-federal laboratory relationships. Part IV explains why these relationships make application of the experimental use exception uncertain.

1. *PATENTING AND LICENSING BY UNIVERSITIES*

Prior to the 1980 and 1984 amendments to the patent laws, patents resulting from federally funded research belonged to the government, who often licensed them on a royalty-free, non-exclusive basis, although policies varied depending on the granting agency.[42] The government had a poor record for advancing the development of its patents. For instance, in 1976, less than four percent of the twenty-eight thousand patents held by the federal government were commercially developed.[43]

The perceived need for the 1980 and 1984 amendments was prompted in part by the concern that federally funded research was not being efficiently commercialized because a company wishing to use that research confronted "a bewildering array of 26 different sets of agency regulations governing their rights to use such research."[44] In response, the amendments created a single, uniform national policy. Non-profit research institutions and small businesses now retain the rights to patents resulting from federally funded research which they perform. The amendments also give universities the right to own inventions made in federally owned research facilities run by the university under contract with the government.

The amendments encourage government-funded researchers to patent resulting inventions by simplifying the bureaucratic obstacles to licensing and by allowing the patent holder to keep the royalties.[45] Private industrial firms can exclusively license these patents from the

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42. James A. Dobkin, *Patent Policy in Government Research and Development Contracts*, 53 VA. L. REV. 564 (1967) (describing policies of the AEC, NASA, the FAA, the Department of Defense, and the Department of Health, Education and Welfare).

43. S. REP. NO. 480, 96th Cong., 1st Sess. 2 (1979).

44. H.R. REP. NO. 1307, 96th Cong., 2d Sess. 2 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6461.

45. *See id.* at 5, *reprinted in* 1980 U.S.C.C.A.N. at 6464.

university or another government contractor for specific uses they intend to commercialize.[46]

Congress designed the amendments to encourage private industry to commit the capital necessary to develop government-funded inventions to the point of commercial application. Supporters of the amendments argue that without the profit incentive provided by exclusive rights, commercial development lags and research results do not become socially useful. The Secretary of Commerce stated, "Direct access to the university and the university's right to transfer the results of its research on an exclusive basis is an important incentive for business to invest in the further development and commercialization of new technologies."[47]

Thus, the patent system accomplishes the policy goal of transferring the products of university research to the publicby allowing a university to license its inventions.[48] However, the license must be exclusive before companies will invest in development. Inventions arising from university research are often at an early stage of development and the licensee may need to do further development simply to identify a commercial product. Because biotechnology products in particular require expensive regulatory approval, it is difficult to find a licensee who is willing to make the required investment without receiving an exclusive license.[49]

In the past the university scientific community viewed private ownership of discoveries as contrary to the university's mission and the public interest.[50] Especially in the biomedical fields, some researchers held a belief that new knowledge should be made as widely available as possible to serve humanity.[51] This attitude has changed for several reasons, making universities increasingly likely to patent publicly and privately funded research.

First, the view that basic research should be freely available to everyone was predicated on the assumption that the work being done

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46. 35 U.S.C. § 202(c)(7) (1988). The government retains a royalty-free worldwide license to practice the invention or have it practiced for the government. *Id.* § 202(c)(4). In addition, the government has march-in rights that terminate the rights of the contractor if the contractor does not effectively attempt to apply the invention. *Id.* 35 U.S.C. §§ 202(c)(8), 203.

47. S. REP. NO. 662, 98th Cong., 2d Sess. 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 5799, 5803.

48. Phyllis S. Lachs, *University Patent Policy*, 10 J.C. & U.L. 263, 276-77 (1983). Of course, this argument assumes that the private sector would not commercially develop the university invention absent an exclusive license.

49. *See* DAVID DICKSON, THE NEW POLITICS OF SCIENCE 91 (1984); Joyce Brinton, *Biotechnology Licensing: Issues from the University Perspective*, 16 AM. INTELL. PROP. L. ASS'N Q.J. 479, 484 (1988).

50. DICKSON, *supra* note 49, at 89-90; BERNARD BARBER, SCIENCE AND THE SOCIAL ORDER 130 (1952).

51. MARTIN KENNEY, BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX 32 (1986).

had no immediate commercial value. When this premise broke down in fields like molecular genetics, and laboratories produced results with commercial value, various entrepreneurial interests insisted that results be privatized.[52] Consequently, patent protection for basic research discoveries with potential commercial value has become more commonplace. This is especially true in biotechnology-related fields where the dividing line between basic and applied research is not clear.[53] Academic and industrial scientists often work on the same or closely related problems.[54]

Second, universities had little incentive to pursue patent rights before the 1980 amendments because the common practice of government agencies supporting the research was to require that the patent be assigned to the government and then freely licensed.[55]

Because the amendments allow the universities to keep royalties, they are looking to licenses as a way to supplement government money for research. As government support of university research has decreased in terms of constant dollars, the cost of scientific research has rapidly escalated.[56] Erich Bloch, then director of NSF, testified before a Senate Committee that the federal government is unable to meet all research needs of the universities and, therefore, the universities have a continuing need for additional funding.[57]

Allowing universities to patent and license faculty inventions has produced a number of success stories for different universities. The Cohen-Boyer gene-splicing patent which forms the basis of the biotechnology industry is expected to bring more than $100 million in royalties to the University of California and Stanford.[58] The Massachusetts Institute of Technology registers more patents than any other university, over one hundred per year, and licenses up to 53% of

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52. *Id.* at 107.

53. DICKSON, *supra* note 49, at 75-76.

54. *Id.* at 74-75; *see* David Blumenthal et al., *Industrial Support of University Research in Biotechnology*, 231 SCIENCE 242 (1986).

55. Dobkin, *supra* note 42, at 568-84, 591-607.

56. Lachs, *supra* note 48, at 268.

57. *National Science and Technology Issues: Hearing Before the Senate Committee on Commerce, Science and Transportation*, 101st Cong., 2nd Sess. 22 (1990) (statement of Erich Bloch, Director, National Science Foundation) [hereinafter *Technology Issues Hearing*]. For instance, the NIH budget has been rising rapidly, from $3.2 billion in 1980 to $7.5 billion in 1990. However, the soaring cost of doing research, the fact that more money is tied up in long-term grants, and the increasing number of scientists applying for grants have created a money drought, especially for younger scientists. NIH research grants account for about 75% of all biomedical research funds provided by the federal government and private nonprofit sources. Gina Kolata, *Beginning Scientists Face a Research Fund Drought*, N.Y. TIMES, June 5, 1990, at C1.

58. Marjorie Shaffer, *All About University Patents: When Research Labs Go After Business*, N.Y. TIMES, Feb. 23, 1992, § 3, at 10; *see also* DICKSON, *supra* note 49, at 90.

those. In 1991, M.I.T. grossed $5.5 million from its licensing activities.[59] Some forty companies employing more than one thousand people have been started based on M.I.T.-licensed technology.[60]

Third, the requirement of the 1980 amendments that universities share royalties with inventors gives researchers an incentive to be alert to patent rights.[61] Universities generally include a patents rights clause in employment contracts with faculty so that the patent must be assigned to the university. Often the university awards between one third and one half of any resulting royalty to the inventor, with the remainder going to the university.[62] Consequently, the inventor profits from any licensing.

2. *UNIVERSITY-INDUSTRY RELATIONSHIPS*

For universities, patents provide more than just royalty income. Patents are also a means of strengthening ties with industry and gaining private support for academic research.

Universities are contracting with industry to conduct specific research with the understanding that the industrial firm receives the right to license and commercially develop the results.

In the past, university-industry agreements were generally of a small scale and seldom controversial.[63] The situation began to change in the mid-1970s at a time when universities experienced economic pressures from rising operating costs coupled with federal funding that failed to keep pace with the expanding number of scientists. In this atmosphere, university faculty and administrators welcomed increased collaboration with and funding from industry.[64] Industrial support of academic research made up only 3.8% of the total university research budget in 1980 but has been generally increasing since then.[65] A 1984 study reveals that industry may be funding as much as one fourth of all biotechnology research in universities.[66] Fueling industry's increased

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59. M.I.T. netted only $500,000 from the $5.5 million it grossed from royalty licenses in 1991 due to the costs associated with filing and licensing patents and the $1 million it distributed to hundreds of individual scientists. Shaffer, *supra* note 58, at 10.

60. *Id.*

61. 35 U.S.C. § 202(c)(7)(C) (1988).

62. Lachs, *supra* note 48, at 281, 285-86 (recommending that universities include a patent rights clause in their employment contracts).

63. DOROTHY NELKIN, SCIENCE AS INTELLECTUAL PROPERTY 18 (1984).

64. *Id.* Universities are partially motivated to accept the corporate sponsorship in order to keep their best scientists, who may move to another university or to industry if denied the corporate funding. KENNEY, *supra* note 51, at 62.

65. KENNEY, *supra* note 51, at 35; NELKIN, *supra* note 63, at 18, 23. Industry contributed $667 million to university research in 1986. Gretchen Morgenson, *In Pecunia Veritas?*, FORBES, Nov. 1988, at 204, 208.

66. Blumenthal et al., *supra* note 54, at 244.

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ARTICLE

SCIENCE AND TOXIC TORTS: IS THERE A RATIONAL SOLUTION TO THE PROBLEM OF CAUSATION?

SUSAN R. POULTER †

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† Associate Professor, University of Utah College of Law; J.D. 1983, University of Utah College of Law; Ph.D., 1969, University of California, Berkeley; B.S. 1965, University of California, Berkeley. The author wishes to thank the following colleagues and friends for their thoughtful review and many helpful comments on drafts of this article: Dean Lee Teitelbaum, Professors Leslie Francis and Wayne McCormack and Associate Professor Paul Cassell of the University of Utah College of Law, and Professor Gary Yost of the Department of Pharmacology and Toxicology of the University of Utah. Any errors are, of course, the author's own.

I. INTRODUCTION

Recent controversies over the safety of breast implants,[1] electrical power transmission lines,[2] and even cellular phones[3] portend yet another period of protracted litigation in which the courts will confront issues of what constitutes admissible and sufficient evidence[4] of causation in toxic torts.[5] Questions have surfaced regarding the safety of each product, but there is no clearly established causal link between chronic exposure to any of them and disease or injury. News reports indicate that while anecdotal reports abound regarding breast implants, little if any systematic testing has been done to confirm suspicions of harmful effects.[6] Concerns about cellular phones were prompted by an even sparser array of anecdotal reports and studies.[7] Electromagnetic radiation from electrical power lines has been studied more extensively, but many scientists remain unconvinced of the purported link between such

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1. *See, e.g.*, Philip J. Hilts, *Experts Suggest U.S. Sharply Limit Breast Implants*, N.Y. TIMES, Feb. 21, 1992, at A1.

2. *See* Bill Richards, *Elusive Threat: Electric Utilities Brace for Cancer Lawsuits Though Risk Is Unclear*, WALL ST. J., Feb. 5, 1993, at A1.

3. *See* Natalie Angier, *Cellular Phone Scare Discounted*, N.Y. TIMES, Feb. 2, 1993, at C1.

4. The United States Supreme Court recently granted the plaintiffs' petition for certiorari in Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991), *cert. granted*, 113 S. Ct. 320 (1992). In *Daubert*, the Ninth Circuit held that animal testing and chemical studies provided insufficient foundation for expert testimony that Bendectin causes limb reduction defects. 951 F.2d at 1131. The court also held that unpublished reanalyses of epidemiologic studies which had not been peer reviewed and which were generated solely for use in litigation were inadmissible on the issue of causation. *Id.*

5. This article uses the term "toxic tort" for cases, including products liability and environmental exposure cases, in which disease or injury is alleged to have resulted from exposure to harmful substances (i.e., chemicals) *See* 1 MICHAEL DORE, THE LAW OF TOXIC TORTS § 2.02 (1992). The toxic tort rubric also applies to cases involving radiation exposure. *See, e.g.*, Allen v. United States, 588 F. Supp. 247 (D. Utah 1984), *rev'd*, 816 F.2d 1417 (10th Cir. 1987), *cert. denied*, 484 U.S. 1004 (1988). For discussion of the characteristics of toxic torts cases, see *infra* notes 43-49 and accompanying text.

6. This statement is intended to apply to the issue of whether breast implants or their constituents pose systemic risks. There are, of course, cases in which the implants have ruptured or produced localized effects, where the injuries and the causal role of breast implants is not subject to the same level of doubt.

As the breast implant controversy came to a head, *Chemical & Engineering News* reported:

> After 30 years of silicone gel breast implant use, the biological, physiological, physical, and chemical reactions of silicones in the human body are likely, finally, to be systematically studied. A major goal of these studies will be determining how often the devices rupture, and what happens when they do.

Lois Ember, *Breast Implants: Silicone Effects in Body to Be Probed*, CHEMICAL & ENGINEERING NEWS, Mar. 2, 1992, at 4. Almost a year later, the *Wall Street Journal* reported that some researchers have identified diseases that they believe are unique to or more common in breast implant recipients. Joan Rigdon, *Breast Implants Raise More Safety Issues: Saline Implants Appear to Carry Hazard as Well*, WALL ST. J., Feb. 4, 1993, at B1.

7. *See infra* notes 10-13 and accompanying text.

exposure and disease.[8] Nonetheless, all three exposures are the subject of recently filed, and in some cases adjudicated, lawsuits.[9]

The current scare over cellular phones is instructive. The primary "evidence" of a causal link between the phones and brain cancer is the fact that a number of cellular phone users have been diagnosed with brain cancer, several with the cancer located near the location of the phone's antenna in use. Using newspaper estimates of over three million users of hand held portable cellular phones in the United States[10] and 11,000 expected deaths from brain cancer this year,[11] it is hardly surprising that several cases of brain cancer in cellular phone users have been reported. One reported laboratory study which reported that radio-frequency radiation increased the growth rate of tumor cells is consistent with the possibility that such radiation could increase the growth rate of preexisting cancers,[12] but it does not prove that there is any effect in humans from cellular phone use.[13]

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8. *See* Richards, *supra* note 2.

9. *Plaintiffs in Georgia, Texas Sue Makers, Contending Devices Caused Various Ailments*, Current Report, Toxics L. Rep. (BNA) 937 (Jan. 8, 1992) (breast implants). On February 4, 1993, the *Wall Street Journal* reported a plaintiffs' lawyer's estimate that 2000 breast implant cases have been or soon will be filed in consolidated court proceedings in Birmingham, Alabama. Rigdon, *supra* note 6. At least one California case produced a verdict for the plaintiff. *Federal Court Upholds $7.3 Million Award, Says Verdict Supported, Punitives Proper*, Toxics L. Rep. (BNA) 1480 (May 6, 1992). Regarding radiation from electrical power transmission lines, see *Suit Seeks to Hold Two Utilities Liable for Injuries to Family Living Near Substation*, Toxics L. Rep. (BNA) 927 (Jan. 8, 1992). *See also* Richards, *supra* note 2, at A1 (describing a "nationwide group of law firms eager to turn [electromagnetic field radiation] into a legal battleground").

Cellular phones are at issue in at least one lawsuit. *See* Angier, *supra* note 3.

10. *See* Stephen Nolhgren et al., *A Lethal Connection?*, ST. PETERSBURG TIMES, Jan. 10, 1993, at 1A (reporting estimates of 10 million owners of cellular phones, approximately one third of which are hand-held portables).

11. *See* Mary Lu Carnevale, *Scientists Doubt Phones Cause Brain Tumors*, WALL ST. J., Feb. 3, 1993, at B1. Richard Adamson, a researcher at the National Cancer Institute, was quoted as predicting 11,800 deaths from brain cancer in the U.S. this year. *Id.* Estimating the population of the U.S. at 250 million, the brain cancer death rate would then be approximately 47 per million, leading to an expected mortality of approximately 140 cases per year among the 3 million hand-held cellular phone users. Even if the age-adjusted cancer rates are lower for the age groups who use cellular phones, it is not unexpected that there would be a number of cases of brain cancer among cellular phone users each year. Further, incidence of brain cancer in the United States is undoubtedly somewhat higher than mortality from the disease.

12. *See supra* note 11.

13. Even the study's author, Stephen Cleary, a physiology and biophysics professor at the Medical College of Virginia, was quoted by the *Wall Street Journal* as stating that he does not believe that portable cellular phones cause cancer. Carnevale, *supra* note 11, at B1. The *Journal* cited scientists from the National Cancer Institute, the Food and Drug Administration, the Environmental Protection Agency, and the Federal Communications Commission as stating that they do not believe that phone use causes brain cancer, but they might pose a small risk of increasing the growth rate of existing cancers. *Id.*

Despite the obvious lack of evidence to prove that cellular phone use causes brain cancer given the current state of knowledge, the evidence available today on cellular phones does not differ substantially in quantity or quality from the evidence that courts have found admissible and sufficient in other recent toxic tort cases. Those problematic cases are likely to be supported only by a combination of anecdotal evidence that amounts to no more than coincidence, speculation in the guise of scientific explanation, and testing based on unvalidated methodology or studies that have limited predictive value for human disease. Sometimes, as in the Bendectin litigation, such evidence is urged upon and accepted by courts in the face of overwhelming scientific consensus, supported by evidence, that a substance is unlikely to be a cause of injury. In other cases, very tenuous evidence is deemed sufficient where more probative positive or negative evidence is unavailable. Such unprobative and insufficient evidence and testimony, termed "junk science" by some observers,[14] has been the subject of increasing commentary and criticism.[15]

Erroneous plaintiffs' verdicts and the corresponding overcompensation and overdeterrence are not just academic concerns. The prospect of useful products being driven from the market or of economic resources being diverted from productive uses is real, as the cases of vaccines[16] and

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14. The term "junk science" has been popularized by Huber. *See* PETER HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991). At least one court has used the term in a toxic tort case as of this writing. Landrigan v. Celotex Corp., 605 A.2d 1079, 1086 (N.J. 1992).

15. *See generally* Bert Black, *A Unified Theory of Scientific Evidence*, 56 FORDHAM L. REV. 595 (1988); Jude P. Dougherty, *Accountability Without Causality: Tort Litigation Reaches Fairy Tale Levels*, 41 CATH. U. L. REV. 1 (1991); Peter Huber, *Junk Science in the Courtroom*, 26 VAL. U. L. REV. 723 (1992). For commentary on the courts' tendency to ignore probative evidence in favor of unproven mechanistic explanations and medical testimony, see Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous Substance Litigation*, 73 CORNELL L. REV. 469 (1988).

16. The cost of litigation and the threat of liability have discouraged research and development of new vaccines, as well as production of existing vaccines, activities that are already of marginal interest to pharmaceutical companies because of high production costs and low return on investment. Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, *in* THE LIABILITY MAZE 335, 341-45 (Peter W. Huber & Robert E. Litan eds., 1991). In 1991, there was only one U.S. manufacturer of vaccines for measles, mumps, rubella, and polio, down from three to six for each. *Id.* at 344. The high price of vaccines for childhood diseases has recently become the focus of public health concerns about low immunization rates among children in the United States. *See* Richard L. Berke, *President Assails "Shocking" Prices of Drug Industry*, N.Y. TIMES, Feb. 13, 1993, § 1, at 1. Those prices are attributable in part to liability concerns. *See* Lasagna, *supra* note 16 at 344; James V. Aquavella, *Profits Don't Explain High Drug Costs*, N.Y. TIMES, Feb. 23, 1993, at A20 (letter to the editor) (attributing high costs to product liability insurance and limited life of patent protection).

Bendectin[17] illustrate. Submission of a case to the jury may result in a plaintiff's verdict where even the most cursory examination of the evidence reveals its deficiencies.[18] Verdicts may be very large,[19] and an occasional plaintiff's verdict may even encourage other suits and increase the settlement value of other cases.[20] The social and economic significance of breast implants, electrical transmission lines and cellular phones varies considerably, but clearly the costs to society of an erroneous conclusion that any of them causes harm are significant, potentially even catastrophic.

To deal with the problems of junk science in court, several commentators have suggested that courts regularize the standard for admissibility of scientific evidence. One frequent suggestion is that courts reinstate or continue to apply the standard announced in *Frye v. United States*,[21] which requires that novel scientific evidence have general acceptance within the relevant scientific discipline,[22] an issue that the United States Supreme Court is expected to address this year in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[23] As will be demonstrated in this article, however, many of the issues that arise are more properly viewed as questions about the sufficiency of relevant evidence to meet the more probable than not standard of proof. Thus, solutions that depend on tightening the criteria for admissibility will either require distortion of the

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17. Bendectin was eventually withdrawn from the market despite defense verdicts in the overwhelming majority of cases. Lasagna, *supra* note 16, at 340; *see also* Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 357 (1992).

18. *See, e.g.*, Ferebee v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). Obviously, no plaintiff's verdict can result where a case is not submitted for a decision on the merits. It is understood among plaintiffs' lawyers that the objective is to get to trial. Thus, plaintiffs often propose to fully try a few "bellwether" cases, while defendants move for exclusion of evidence and summary judgment on causation issues. *See, e.g.*, Renaud v. Martin Marietta Corp., 749 F. Supp. 1545, 1547 (D. Colo. 1990), *aff'd*, 972 F.2d 304 (10th Cir. 1992).

19. In Ealy v. Richardson-Merrell, Inc., Civ. A. No. 83-3504, 1987 WL 18743 (D.D.C. Oct. 1, 1987), *rev'd*, 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 498 U.S. 950 (1990), the jury awarded compensatory damages of $20 million and punitive damages of $75 million to a boy born with limb reduction defects attributed to Bendectin. The district court allowed the compensatory verdict to stand, but granted remittitur as to the punitive verdict. The compensatory verdict was reversed on appeal.

20. *See* Sanders, *supra* note 17, at 357.

21. 293 F. 1013 (D.C. Cir. 1923).

22. *See, e.g.*, Black, *supra* note 15, at 637-38; Huber, *supra* note 15, at 742-47. The *Frye* rule is still followed in many jurisdictions. *See, e.g.*, Christopherson v. Allied-Signal Corp., 939 F.2d 1106, 1110 (5th Cir. 1991) (en banc), *cert. denied*, 112 S. Ct. 1280 (1992). *See generally* Black, *supra* note 15, at 601 & n.23. *Frye* was also the basis of rejection of certain of plaintiffs' evidence in Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991), *cert. granted*, 113 S. Ct 320 (1992). See discussion of *Frye infra* notes 55-61 and accompanying text.

23. 951 F.2d 1128 (9th Cir. 1991), *cert. granted*, 113 S. Ct. 320 (1992).

admissibility inquiry to encompass sufficiency issues, or will address only part of the problem. Similar concerns are raised by proposals to change the rules of evidence to limit the use of expert testimony.[24]

The problem of determining the sufficiency of evidence of causation is more directly addressed by proposals that courts use science boards, science panels or court-appointed experts to assist in resolving scientific issues.[25] Such proposals, however, except for the use of court-appointed experts, depart substantially from existing notions of civil jurisprudence because they involve delegation to experts of the traditional fact-finding functions of the lay trier of fact.

The thesis of this article is that measures such as the return to the *Frye* rule, or the use of science panels or science courts are unnecessary, because common law courts already possess the authority under the existing rules to "actively review"[26] scientific evidence by eliciting and scrutinizing the reasoning underlying scientific evidence and expert testimony and determining its validity and probative worth. As this article will demonstrate, much of the junk science that appears in toxic tort cases is readily apparent or easily uncovered by inquiry of which courts are quite capable.

If active review under the existing rules can uncover bad science, why do a significant number of courts take a lenient posture toward scientific evidence? There appear to be two major reasons for the deferential approach. First, some courts are philosophically indisposed to examine scientific reasoning or methodology, fearing that they are ill-

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24. A working group of the Judicial Conference proposed the following amendment of Rule 702 of the Federal Rules of Evidence:

> Testimony providing scientific, technical, or other specialized information, in the form of an opinion or otherwise, may be permitted only if (1) the information is reasonably reliable and will substantially assist the trier of fact to understand the evidence or to determine a fact in issue, and (2) the witness is qualified as an expert by knowledge, skill, experience, training, or education to provide such testimony. Except with leave of court for good cause shown, the witness shall not testify on direct examination in any civil action to any opinion or inference, or reason or basis therefor, that has not been seasonably disclosed as required by Rules 26(a)(2) and 26(e)(1) of the Federal Rules of Civil Procedure.

137 F.R.D. 83 (1991). The proposed changes seem more a shift in emphasis than a radical revision of the existing rule. *See also* Black, *supra* note 15, at 611-13 (proposing a modification of Rule 702 to require the court to determine the validity of reasoning as well as its reliability as a precondition to admitting scientific evidence).

25. *See* 2 AMERICAN LAW INST. REPORTERS' STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY, APPROACHES TO LEGAL AND INSTITUTIONAL CHANGE 332-51 (1991). The ALI Reporters' Study recommendations were based on Brennan,, *supra* note 15, and Troyen Brennan, *Helping Courts with Toxic Torts: Some Proposals Regarding Alternative Methods for Presenting and Assessing Scientific Evidence in Common Law Courts*, 51 U. PITT. L. REV. 1 (1989).

26. For a discussion of "active review," see Black, *supra* note 15, at 674-77.

equipped to delve into scientific disciplines. As will be described below, however, scientific reasoning and legal factfinding employ the same rules of logic. Thus, lay judges need not fear that examination of scientific evidence to determine whether it is soundly reasoned and reliable is beyond their capabilities.

Moreover, the reasons for judicial control of evidence are more compelling where technical evidence is concerned than for non-technical evidence. Judges exhibit no hesitation in barring non-expert testimony based on hearsay and otherwise lacking in foundation even though juries could readily identify the flaws in such testimony with skilled cross-examination and argument by opposing counsel. Juries are less likely to identify the weaknesses in testimony cloaked in technical jargon from an expert with a lengthy list of credentials than in testimony on ordinary factual issues.[27] Thus, it is more important for the judge, who understands the legal requirements of proof, to discriminate between reliable and unreliable scientific evidence than between well founded and unfounded evidence on matters within the understanding of ordinary people.[28]

A second reason for the lenient treatment of scientific evidence in some courts is the apparent desire to compensate for perceived inequities and deficiencies of the tort system. Much of the movement toward the adoption of lenient standards of admissibility and proof of causation in toxic torts has been prompted by the recognition of the difficulties faced by plaintiffs in meeting the traditional requirement that they prove, by a preponderance of the evidence, that their injuries were caused by chronic, low-level chemical or radiation exposures that were remote in time from the manifestation of injury. The paucity of scientific evidence on the causation of diseases such as cancer and birth defects, and the difficulty of distinguishing other identified or background risk factors for the disease, decrease the likelihood that deserving plaintiffs will be compensated. The level of concern about those difficulties was heightened by increasing scientific knowledge of the role of chemicals and radiation in diseases such as cancer and birth defects, as well as scientific speculation about

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27. Courts that scrutinize scientific evidence more closely recognize that jurors are likely to be persuaded by the aura of infallibility that surrounds scientific evidence, or by the credentials and certainty expressed by the expert. *See* Barefoot v. Estelle, 463 U.S. 880, 926-28 (1983) (Blackmun, J., dissenting).

28. Courts' abandonment of the *Frye* standard increases the need for judicial scrutiny of scientific evidence because the *Frye* general acceptance standard assures that some evaluation of methods or theories other than that of the expert witness has occurred. Once courts unhinge the admissibility of scientific evidence from scientists' standards, it is incumbent on them to see that other safeguards are in place. *See* Steven M. Egesdal, Note, *The* Frye *Doctrine and Relevancy Approach Controversy*, 74 GEO. L.J. 1769, 1787 (1986) (suggesting the need to increase jurors' understanding of novel scientific techniques under the relevancy approach).

potential effects of the greatly accelerated dissemination of untested new chemicals in consumer products and the environment.[29] Taking their cue from the scientists,[30] legal scholars began to address the difficulties faced by plaintiffs in proving that exposure to toxic substances or chemicals caused their diseases or injuries,[31] difficulties that can result in uncompensated injuries and the failure to adequately deter harmful activity.[32] Lenient standards of admissibility and proof certainly facilitate plaintiffs' recoveries; further, they are consistent with courts' suspicions that mainstream scientists are too demanding in their requirements of proof, and that the unconventional scientists who testify that an exposure caused a plaintiff's disease may be correct.

More than a decade of scientific research into cancer incidence and causation, however, has failed to bear out the fears that prompted deferential review of causation evidence. Many of the assumptions that underlay the shift to more lenient standards for causation evidence in toxic torts are still unproven or are even contrary to current scientific thinking. The contribution of toxic synthetic chemicals and other hazards of the industrial age to cancer and other diseases and injuries is still an open question, but it appears unlikely that such substances cause anything approaching a majority of human cancer and birth defects.

As for the possibility that the unconventional expert may be right, even a superficial examination of much of the disputed evidence reveals that it amounts to speculation about possibilities that have not been tested or that fall far short of meeting the more probable than not standard of proof. Speculation about possibilities forms the beginning, not the endpoint, of factual inquiry, in either the scientific or legal realm. A causal explanation of disease or injury can be said to be probable only when it is supported by observations or data that distinguish between it and other possible explanations. When courts authorize or approve plaintiffs' verdicts without a factual basis for causal inference, they undermine traditional tort requirements for rational factfinding and the "more probable than not" standard of proof. The case for the abrogation of those standards has not been made, nor have courts given full consideration to the implications of such a radical change in the law.

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29. *See* Bruce N. Ames, *Identifying Environmental Chemicals Causing Mutations and Cancer*, 204 SCIENCE 587, 588-89 (1979).

30. *See, e.g., id.* at 592 (recommending short-term mutagenicity testing to expedite identification of environmental mutagens and carcinogens).

31. *See, e.g.*, Jeffrey Trauberman, *Statutory Reform of "Toxic Torts": Relieving Legal, Scientific and Economic Burdens on the Chemical Victim*, 7 HARV. ENVTL. L. REV. 177, 188 n.48 (1983) (citing law review articles and other writings).

32. *See generally* David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 849 (1984).

The purpose of this Article is to demonstrate that courts can and should actively review scientific evidence of causation in toxic tort cases. The next Part describes how courts have loosened the standards for expert testimony in an effort to compensate for the perceived problems faced by toxic tort plaintiffs. Part III then discusses active review and its relation to the rules of evidence and civil procedure and attempts to allay courts' fears that they are ill equipped to evaluate the basis of scientific opinion testimony. Part IV then describes the criteria against which the reliability of scientific evidence can be evaluated and then applies those criteria to the kinds of evidence offered on causation in toxic tort suits. Part V examines a sampling of recent cases that illustrate inadequate judicial scrutiny of scientific evidence, as well as cases that skillfully distinguish probative from nonprobative or insufficient evidence. Lastly, Part VI discusses in depth the factors that underlie courts' failure to examine adequately scientific evidence and shows that many of those concerns are unjustified or that, even where justified, the remedy of authorizing plaintiffs' verdicts that are unsupported by a factual foundation goes too far.

II. HARD CASES MAKE BAD LAW

In the 1960s and 1970s, mounting evidence on the harmful effects of chemicals such as asbestos, vinyl chloride, dioxin and many others, together with the dramatic increase in the use of new chemicals in products ranging from foods, to drugs and medical devices, to many other consumer products, raised concerns that chronic, low level exposures to those substances would lead, or might already have led, to widespread illness and injury.[33] As evidence mounted that exposure to substances such as asbestos and vinyl chloride could cause cancer and other debilitating or fatal conditions, the courts began to see an increasing number of toxic tort suits—tort actions seeking to recover for injuries attributed to toxic substances.

As numerous commentators have explained, proof of causation[34] has been the biggest stumbling block to recovery in toxic torts cases.[35]

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33. *See* R. Jeffrey Smith, *Government Says Cancer Rate Is Increasing*, 209 SCIENCE 998 (1980); Mostafa K. Tolba, *Chemicals in the Environment*, 1979 NAT'L PARKS & CONSERVATION MAG. 16. The controversy continues, as indicated by more recent publications. *See* Eliot Marshall, *Experts Clash over Cancer Data*, 250 SCIENCE 900 (1990); *see also infra* notes 332-38 and accompanying text.

34. This Article is addressed to issues of causation in fact, by which is meant the issue of whether there is an empirical linkage between the causative event and the claimed injury.

35. *See* Brennan, *supra* note 25, at 2; Daniel A. Farber, *Toxic Causation*, 71 MINN. L. REV. 1219, 1219-20 (1987); Jean M. Eggen, *Toxic Reproductive and Genetic Hazards in the Workplace: Challenging the Myths of the Tort and Worker's Compensation System*, 60 FORDHAM L. REV. 843, 861-64 (1992) (discussing causation problems in the worker's compensation system);

Both negligence and strict liability require the plaintiff to prove that the substance in question[36] caused the plaintiff's disease or injury.[37] That inquiry often involves a number of subissues,[38] including whether: (1) the toxic substance is capable of causing the harm complained of[39]; (2) the plaintiff was exposed to the toxic substance in quantity sufficient to cause disease,[40] and (3) the toxic substance exposure caused the particular plaintiff's injury or disease.[41] Proof of any of these propositions is likely to require expert testimony on scientific evidence.[42]

Palma J. Strand, Note, *The Inapplicability of Traditional Tort Analysis to Environmental Risks: The Example of Toxic Waste Pollution Victim Compensation*, 35 STAN. L. REV. 575, 583-84 (1983); Note, *Tort Actions for Cancer: Deterrence, Compensation, and Environmental Carcinogenesis*, 90 YALE L.J. 840 (1981) (hereinafter Note, *Tort Actions for Cancer*).

36. Disputes over who produced the offending substance have also been cast as causation questions. These "indeterminate defendant" cases have arisen frequently in asbestos and DES litigation where the plaintiff may have difficulty identifying the producer of the substance to which the plaintiff was exposed, even where the causal connection between the substance and the injury is established. *See* Richard Delgado, *Beyond* Sindell*: Relaxation of Cause-in-Fact Rules for Indeterminate Plaintiffs*, 70 CAL. L. REV. 881 (1982); Eggen, *supra* note 35, at 890-91 & n.258.

37. Most courts require proof of causation to meet a "more likely than not" standard. *See, e.g.*, Renaud v. Martin Marietta Corp., 749 F. Supp. 1545, 1553 (D. Colo. 1990), *aff'd*, 972 F.2d 304 (10th Cir. 1992). *See generally* Bert Black & David E. Lilienfeld, *Epidemiologic Proof in Toxic Tort Litigation*, 52 FORDHAM L. REV. 732, 749-50 (1984). *But see* Black, *supra* note 15, at 659-69 (discussing the meaning of "reasonable medical certainty"). Additionally, most jurisdictions require the plaintiff to prove that her injuries would not have occurred "but for" the exposure to the toxic substance. Brennan, *supra* note 15, at 493-94. Where there are two or more contributing causes to a single harm, some courts will require proof only that the exposure was a "substantial factor" in causing the plaintiff's injury or that it "contributed to" the plaintiff's injury. *See* Renaud v. Martin Marietta Corp., 749 F. Supp. at 1551 (plaintiff must prove that "the exposure caused, or contributed to, plaintiff's injuries"). Proof under the substantial-or-contributing-factor test nonetheless requires establishment of a "but for" causal relationship between the substance and the plaintiff's disease. *See* Bert Black et al., *Unravelling Causation: Back to the Basics*, 7 Toxics L. Rep. (BNA) 1061, 1063 (1993). A somewhat different formulation, perhaps more suited to the realities of toxic torts, is Calabresi's "causal linkage," that is, the belief that the causative event makes the occurrence of the injury result more likely. *See* Guido Calabresi, *Concerning Cause and the Law of Torts: An Essay for Harry Kalven, Jr.*, 43 U. CHI. L. REV. 69, 71 (1975).

38. *See* Black & Lilienfeld, *supra* note 37, at 737-38.

39. *See* Black, *supra* note 15, at 689. Although this framing of the question seems implicit, plaintiffs sometimes argue that evidence of causation of one type of harm is evidence of causation of other types of harm. *Id.*; *see also* Christopherson v. Allied-Signal Corp., 939 F.2d 1106, 1115 (5th Cir. 1991) (en banc) (association of nickel and cadmium with small-cell carcinoma of the lung asserted as probative of causation of small-cell colon cancer), *cert. denied*, 112 S. Ct. 1280 (1992).

40. *See* Black & Lilienfeld, *supra* note 37, at 737-38. Courts sometimes frame the question more simply as whether the plaintiff was exposed to the toxic substance, and there is some divergence in the case law as to the specificity with which exposure must be proved. *See infra* notes 219-20 and accompanying text.

41. This statement, which appears all-inclusive, is intended to cover those aspects of causation-in-fact that remain after exposure and capability of the substance to cause harm ("general causation") are established, including primarily the issue of whether plaintiff's

Several characteristics of the typical toxic tort case diminish the prospects of recovery by deserving plaintiffs.[43] The long latency period between exposure and disease manifestation[44] decreases the likelihood that the plaintiff will even suspect the causal connection, as well as decreasing the likelihood that the plaintiff will be able to marshal the facts on issues such as exposure necessary to prove her case.[45] Typically there is no clinical evidence capable of linking the substance to the disease.[46] The situation is further complicated by the fact that exposure to the toxic

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injury was the result of the toxic substance exposure or other causes. This issue is sometimes referred to as one of "individual causation" or "medical causation." Renaud v. Martin Marietta Corp., 972 F.2d 304, 306 (10th Cir. 1992) (discussing medical causation); *see also* Rosenberg, *supra* note 32, at 855-56 (discussing "specific causation").

42. *See, e.g., In re* Paoli R.R. Yard PCB Litig., 916 F.2d 829 (3d Cir. 1990) (plaintiff's case depended upon expert testimony relating to exposure and causation), *cert. denied*, 111 S. Ct. 1584 (1991); Renaud v. Martin Marietta Corp., 749 F. Supp. 1545 (D. Colo. 1990) (expert testimony on exposure and individual causation), *aff'd*, 972 F.2d 304 (10th Cir. 1992). As a definitional matter, this Article will use the terms science and scientific evidence to encompass both science, in the sense of discovery of new factual information, and technology, which can be defined as application of established scientific principles to a particular problem. *See* Howard T. Markey, *Needed: A Judicial Welcome for Technology—Star Wars or Stare Decisis?*, 79 F.R.D. 209, 210-12 (1978). An additional assumption will be made that scientific evidence will be presented by expert witnesses, because that is most often the case.

43. *See generally* Brennan, *supra* note 25, at 20-26 (discussing cancer causation); Strand, *supra* note 35, at 578-86.

44. *See* Strand, *supra* note 35 at 580-81. More precisely, the lapse of time between exposure and the appearance of clinical symptoms may comprise both an induction period, the period of time between the exposure and disease initiation, and a latency period, the interval between disease occurrence and detection. *See* KENNETH J. ROTHMAN, MODERN EPIDEMIOLOGY 14-15 (1986). The period between first exposure and clinically detectible disease for many cancers is 20 to 30 years. Ames, *supra* note 29, at 587. Birth defects that are manifest at birth or soon thereafter would not exemplify this problem to nearly as great a degree.

45. Delay may, however, may increase the chance that epidemiologic evidence will be available. Nonetheless, latency also gives rise to problems under some formulations of statutes of limitation, although many jurisdictions employ the discovery rule to determine when the statute of limitations begins to run. *See* Black & Lilienfeld, *supra* note 37, at 780; Strand, *supra* note 35, at 580-81.

46. In cases involving "signature diseases," diseases that are almost exclusively associated with a toxic substance, the presence of the condition is highly probative of the causative agent. Examples of signature diseases are mesothelioma, associated almost entirely with asbestos exposure, and clear cell adenocarcinoma of the vagina, associated almost exclusively with diethylstilbestrol (DES) exposure in utero. *See* Brennan, *supra* note 25, at 21 & n.96. In most cases, however, either the toxic substance is no longer present when the disease manifests itself, as is the case with benzene and leukemia, or its presence, if persistent, is not the only or even most probable explanation of disease. *See* Brennan, *supra* note 15, at 502. An example of the latter is the almost ubiquitous presence of PCBs in human adipose tissue, apparently without effect in most cases. *See In re* Paoli R.R. Yard PCB Litig., 916 F.2d 829, 843 (3d Cir. 1990) (discussing ATSDR studies), *cert. denied*, 111 S. Ct. 1584 1991). *But see* Landrigan v. Celotex Corp., 605 A.2d 1079, 1087 (N.J. 1992) (discussing the presence of asbestos near the tumor as probative of colon cancer causation).

substance, even at relatively high levels, may not result in disease in most persons.[47] Moreover, many of the diseases caused by toxic chemicals, particularly cancers and birth defects, occur in the general population.[48] The absence of any unequivocal linkage between the disease and the toxin, together with the absence of clinical tests that could establish a linkage, means that proof of causation, if it can be made out at all, must be made indirectly, from comparisons between exposed and unexposed groups, or from studies where surrogates such as animals or single-celled organisms are used. Further, there may be other known risk factors for the claimed injury, whose role in the disease process must be considered.[49]

The obvious difficulties of proof in toxic tort cases provoked a flood of commentary and proposals for reform.[50] A number of commentators have focused specifically on limitations placed by courts on the kinds of

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47.Occupational asbestos exposure in nonsmokers increases the risk of lung cancer by about a factor of five, from about 11 per 100,000, for nonsmoking industrial workers not exposed to asbestos, to about 58 per 100,000 for nonsmoking asbestos workers. *See* U.S. SURGEON GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. 85-50207, HEALTH CONSEQUENCES OF SMOKING: CANCER AND CHRONIC LUNG DISEASE IN THE WORKPLACE 216 (1985); *see also* Rodolfo Saracci, *The Interactions of Tobacco Smoking and Other Agents in Cancer Etiology*, EPIDEMIOLOGIC REVS. 175, 181-83 (1987).

48.*See, e.g.*, Rubanick v. Witco Chem. Corp., 593 A.2d 733, 745 (N.J. 1991) (involving contention that PCB exposure caused colon cancer). Colorectal cancer is the second most common cancer in the United States. *Colonoscopy Recommended*, AM. MED. NEWS, Sept. 16, 1991, at 39, *cited in Landrigan*, 605 A.2d at 1082).

49.For example, although asbestos is recognized as a cause of lung cancer, *see supra* note 47, other causative factors such as smoking are well known. That fact often leads to contentions that the plaintiff's disease was caused by factors other than the toxic chemical exposure. For discussion of attributable risk and the problems of distinguishing among causes, see *infra* notes 206-18 and accompanying text.

50.Some commentators have proposed modification of the tort system's rules of liability, suggesting, for example, that courts recognize causes of action for tortiously created risk. *See, e.g.*, Glen O. Robinson, *Probabilistic Causation and Compensation for Tortious Risk*, 14 J. LEGAL STUD. 779 (1985) [hereinafter Robinson, *Probabilistic Causation*]. Others have suggested that all victims of a disease attributable in part to toxic chemical exposure recover the fraction of their damages that corresponds to the proportion of disease incidence attributable to the toxic exposure. *See, e.g.*, Delgado, *supra* note 36, at 892; Glen O. Robinson, *Multiple Causation in Tort Law: Reflections on the DES Cases*, 68 VA. L. REV. 713, 759 (1982); Rosenberg, *supra* note 32; *cf.* Farber, *supra* note 35, at 1221 (proposing compensation for the "most likely victim"). A number of courts have redefined damages or injury to include exposure, presumed subclinical injury, medical monitoring costs, or fear of cancer where clinically manifest disease or injury is absent. *See* 2 DORE, *supra* note 5, §2.02.

Other commentators have recommended the shifting burden of proving causation to defendants, once a threshold showing is made of the possibility of harm. *See* Note, *Tort Actions for Cancer*, *supra* note 35, at 855-62. Still others have suggested administrative compensation systems with reduced requirements for proof of causation. *See* Black & Lilienfeld, *supra* note 37, at 734 & nn.3-5 (discussing the Superfund Study Group's proposal for an administrative compensation scheme); *see also* E. Donald Elliott, *Why Courts? Comment on Robinson*, 14 J. LEGAL STUD. 799, 801 (1985).

evidence deemed admissible or sufficient to prove causation. One set of problems has been courts' reluctance to accept statistical evidence, such as epidemiologic studies, because statistical evidence does not provide mechanistic explanations of cause and because statistics do not provide a basis for distinguishing between persons in an exposed group whose disease was caused by the exposure from those whose disease was caused by background or other risk factors.[51] Recognizing that epidemiologic evidence is often the best if not the only evidence linking a toxic substance exposure to disease, however, recent cases have been more accepting of epidemiologic evidence,[52] in some cases evidencing quite a sophisticated understanding of epidemiologic evidence.[53]

Other commentators have urged courts to liberalize the standards for admissibility of scientific evidence in general.[54] They have suggested that the traditional requirement under *United States v. Frye* that limits the admission of scientific evidence to that generally accepted in the relevant scientific discipline[55] may preclude recovery by deserving plaintiffs who

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51. *See, e.g.*, Black & Lilienfeld, *supra* note 37, at 767; Brennan, *supra* note 15, at 491-501.

52. *See, e.g.*, Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 313 (5th Cir.) (holding absence of "conclusive" epidemiologic evidence fatal to plaintiffs' case), *modified*, 884 F.2d 166, 167 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990). The Fifth Circuit subsequently modified *Brock*, stating that the plaintiffs' case was fatally flawed because of their failure to present "statistically significant" epidemiologic evidence. Brock v. Merrell Dow Pharmaceuticals, Inc., 884 F.2d 166, 167 (5th Cir. 1989) (denying plaintiffs' motion for rehearing en banc and modifying prior opinion), *cert. denied*, 494 U.S. 1046 (1990). Courts willing to accept statistical evidence as probative of the capability of a substance to cause harm have sometimes balked at accepting such evidence on the question of whether the substance caused the *plaintiff's* injury, on the basis the epidemiologic evidence cannot prove individual causation. *See, e.g.*, Landrigan v. Celotex Corp., 605 A.2d 1079, 1087 (N.J. 1992) (discussing the trial court's refusal to allow an epidemiologist to testify on individual causation). In *Landrigan*, the New Jersey Supreme Court, however, set forth a detailed summary of how epidemiologic reasoning could be applied to the question of individual causation and concluded that an epidemiologist could offer an opinion on that issue, provided the expert's qualifications and methodology withstood the trial court's scrutiny. *Id.* at 1087-89.

53. *See, e.g.*, DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 946-49 (3d Cir. 1990) (discussing statistical significance); *Landrigan*, 605 A.2d at 1087 (discussing the concept of attributable risk derived from epidemiologic studies). Several courts have announced that epidemiologic evidence is the only sufficient evidence on the question of whether Bendectin causes human birth defects. *See, e.g., Brock*, 874 F.2d at 313-15.

54. Anne S. Toker, *Admitting Scientific Evidence in Toxic Tort Litigation*, 15 HARV. ENVTL. L. REV. 165 *passim* (1991); *see also citations in* Rubanick v. Witco Chem. Corp., 593 A.2d 733, 740 (N.J. 1991).

55. The traditional standard for determining the admissibility of novel scientific evidence was set forth in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923). The *Frye* court stated, in regard to evidence based on a forerunner of modern polygraph testing, that "the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field to which it belongs." *Id.* at 1014. The *Frye* test is most appropriately applied to the expert's methodology or reasoning, including but not limited to devices or techniques such as the breathalyzer or polygraph. *See* Black, *supra* note 15, at 627-29. It is sometimes applied to the expert's opinion or conclusions, however,

must rely on novel, yet valid and reliable evidence.[56] That line of reasoning was accepted in *Ferebee v. Chevron Chemical Company*,[57] in which the Court of Appeals for the District of Columbia Circuit upheld a jury verdict of liability based on expert opinion testimony on causation that did not enjoy general acceptance in the scientific community.[58]

Ferebee coincided with a general move away from the *Frye* standard under the Federal Rules of Evidence toward the relevancy or reliability test articulated in *United States v. Downing*.[59] In *Downing*, the Third Circuit stated that the admissibility of scientific evidence should focus on the soundness and reliability of the expert's methodology, the strength of the connection between the evidence and the issues in the case, and the possibility of confusing or misleading the jury.[60] Acceptance of the

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in such cases being stated to require that the expert's opinion or theory be generally accepted by the relevant scientific community. *See, e.g.*, Rubanick v. Witco Chem. Corp., 542 A.2d 975, 982 (N.J. Super. Ct. Law Div. 1988) (applying *Frye* analysis to scientific principle on which expert's opinion was based), *rev'd*, 576 A.2d 4 (N.J. Super. Ct. 1990), *modified*, 593 A.2d 733 (N.J. 1991); *see also* Black, *supra* note 15, at 629-38. Contrarily, some commentators have taken the position *Frye*'s general acceptance test should not be applied to an expert's reasoning or methodology, but only to particular techniques or devices. *See, e.g.*, Christopherson v. Allied-Signal Corp., 939 F.2d 1106, 1131-33 (5th Cir. 1991) (Rawley, J., dissenting), *cert. denied*, 112 S. Ct. 1280 (1992). Many jurisdictions still follow *Frye*. *See, e.g., Christopherson*, 939 F.2d 1106.

56. *Frye* has proven to be a significant barrier to novel scientific theories and methodologies. Edward J. Imwinkelreid, *The Standard for Admitting Scientific Evidence: A Critique from the Perspective of Juror Psychology*, 28 VILL. L. REV. 554, 555-56 (1982-83). As Huber has pointed out, however, when the *Frye* inquiry is directed to the methodology and reasoning underlying scientific opinion, a novel opinion on causation will easily pass muster if it is based on well-established and properly conducted methods, such as epidemiologic studies. Huber, *supra* note 15, at 744.

57. *See* Ferebee v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984).

58. *Id.* at 1535-36. The *Ferebee* court did not reject *Frye* out of hand, however, but construed it as applicable only to novel techniques or methodologies, not scientific opinion testimony. *Id.* at 1535.

59. 753 F.2d 1224 (3d Cir. 1985); *see also In re* Paoli R.R. Yard PCB Litig., 916 F.2d 829, 856-60 (3d Cir. 1990), *cert. denied*, 111 S. Ct. 1584 (1991); *In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1242 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988); Rubanick v Witco Chem. Corp., 593 A.2d 733, 746 (N.J. 1991).

60. In *Downing*, the Third Circuit articulated the proper test as follows:

> In our view, Rule 702 [of the Federal Rules of Evidence] requires that a district court ruling upon the admission of (novel) scientific evidence . . . conduct a preliminary inquiry focusing on (1) the soundness and reliability of the process or technique used in generating the evidence, (2) the possibility that admitting the evidence would overwhelmingly confuse or mislead the jury, and (3) the proffered connection between the scientific research or test result to be presented and the particular disputed factual issues in the case.

Downing, 753 F.2d at 1238. The *Downing* reliability standard is inherently more flexible than *Frye* because it is not tied to "general acceptance." Nonetheless, courts recognize that acceptance in the expert community is an important indicium of reliability. *See, e.g., id.*

expert's techniques or methodology in the relevant scientific community is evidence of soundness, but need not be the sole basis for that determination.

Although *Frye* has been justifiably criticized as too simplistic and inflexible,[61] the *Downing* standard is equally problematic when it is used to justify such minimal scrutiny of the reliability of scientific evidence, particularly of expert opinion testimony, that it amounts to no standard at all. The troublesome, deferential application of the reliability standard adopts the approach that if "qualified" experts are willing to testify that a causal relationship exists, the court is willing to uphold a plaintiff's verdict without examining whether a reasoned basis exists for the expert's opinion.[62] This approach is undoubtedly the result of some courts' reluctance to delve into the reasoning underlying scientific evidence, a reluctance that results in deference to the expert with seemingly impressive credentials. The crucial determination then becomes whether the expert is qualified, a particularly weak screening device given the lenient standards for determining expert qualifications.[63]

Deferential review is the gateway for the admission of junk science into the courts. When courts do not examine the reasoning of expert testimony, they are likely to accept medical opinion based on the facts in the case at hand, or supported by perhaps a few other case reports, facts

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Thus, the *Frye* standard is related to reliability, though more limiting. *See generally* Imwinkelried, *supra* note 56.

61. Part of the difficulty with the *Frye* rule is the lack of consensus regarding the subject matter to which it applies. For example, is it the expert's opinion, the reasoning or methodology that underlies the opinion, or both that must be generally accepted? *See supra* note 55. The better rule would seem to be that the *Frye* general acceptance test applies to the expert's reasoning and methodology, but not to the opinion or conclusion derived from that methodology. Otherwise, the *Frye* rule effectively delegates part of the admissibility determination to the scientific discipline, obviating the need for the court to evaluate the expert's reasoning or methodology. On the other hand, as Black has pointed out, the general acceptance test of *Frye* is not an appropriate standard to apply to the uncertainty or accuracy (i.e., the reliability) of scientific methodology. *See* Black, *supra* note 15, at 629-57. The Ninth Circuit's opinion in Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991), *cert. granted*, 113 S. Ct. 320 (1992), appears to commit this error, when it frames the admissibility standard regarding an unpublished, un-peer-reviewed reanalysis of epidemiologic data as follows: "Expert opinion based on a scientific technique 'is admissible if it is generally accepted as a reliable technique among the scientific community.' " *Id.* at 1129 (quoting United States v. Solomon, 753 F.2d 1522, 1526 (9th Cir. 1985)).

62. Ferebee v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 429 U.S. 1062 (1984), is the leading case following this approach and is often cited by other courts taking similar approaches. In *Ferebee*, the Court of Appeals for the District of Columbia Circuit upheld a jury verdict for the plaintiff where testimony of causation was based on "tissue samples, standard tests, and patient examination." *Id.* at 1536. There is nothing in the opinion to suggest that the cited tests and examinations were capable of indicating the cause of the lung disease complained of, however.

63. FED. R. EVID. 702 provides that a witness may be qualified as an expert "by knowledge, skill, experience or training."

that cannot establish causation because the coincidence of exposure and disease may be the result of chance.[64] In some cases, courts accept as sufficient medical or similar opinions supplemented by reference to animal studies, chemical structure-activity analyses, mutagenicity testing, or other similar lines of reasoning that are subject to a large degree of uncertainty.[65] Affirmative epidemiologic evidence of a statistically significant association between the alleged causative agent and human disease is absent.[66] As a practical matter, only those cases based on studies in human populations of the association of suspected toxic substances and disease—e.g., epidemiologic studies or highly unusual disease clusters—have proven to be sound as new scientific information developed.[67]

A reliability analysis should not result in uncritical acceptance of junk science.[68] Tort jurisprudence requires that there be a rational basis

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64. *See, e.g., Ferebee*, 736 F.2d at 1535.

65. *See, e.g.*, Rubanick v. Witco Chem. Corp., 593 A.2d 733, 735-36 (N.J. 1991) (expert based opinion that PCBs caused plaintiff's colon cancer on animal test reports and other cancer cases at Witco). The Bendectin litigation has been characterized by plaintiffs' cases based on animal testing, structure-activity relationships, *in vitro* testing, and reanalysis of data from epidemiologic studies that failed to show statistically significant increased risks. *See, e.g.*, Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990). *See generally* Sanders, *supra* note 17. Brennan in particular has urged courts to admit animal studies and other methods used in cancer and other medical research. Brennan, *supra* note 25, at 41-57; *see also* Michael D. Green, *Expert Witnesses and Sufficiency of the Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and the Bendectin Litigation*, 86 NW. U. L. REV. 643, 680-81 (1992).

66. Occasionally, plaintiffs may offer a "reanalysis" of existing epidemiologic data. *See infra* notes 350-58.

67. It may be tempting to characterize the argument made herein as establishing a threshold requirement of epidemiologic evidence to support a toxic tort case. A number of commentators have characterized Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990), and cases that have followed it as creating such a threshold in Bendectin cases. *See, e.g.*, Green, *supra* note 65, at 679-82. The intent of this Article, however, is to show why, given the present state of toxicological science, anecdotal evidence, animal test results, and other evidence offered when positive human evidence is missing are generally unreliable and insufficiently probative in the typical toxic torts case. The kind of analysis proposed herein can be applied to new information as it develops, without the rigidity of a per se rule about specific kinds of evidence.

68. In *In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988), Judge Weinstein excluded the causation opinion testimony of several of plaintiffs' witnesses because he concluded that their testimony, which relied on animal tests and studies of industrial exposures, and which failed to consider and eliminate other causal explanations, was "insufficiently grounded in any reliable evidence." *Id.* at 1248-51. Although Judge Weinstein cited Rule 703 as the basis of his ruling, *see id.* at 1243-55, it is clear that he recognized the uncertainty associated with causal inferences derived from animal studies or human studies where exposures differed widely from plaintiffs', particularly where the experts ignored more relevant studies and alternative causal explanations. *See id.* at 1250. Under the analysis proposed in this Article, the factors cited by Judge Weinstein would be part of a reliability

for judicial findings of fact.[69] The relevancy or reliability standard's "soundness and reliability" inquiries bear directly on whether there is a rational basis for findings of fact and whether the evidence is sufficient to meet the more probable than not standard of proof.[70] Active review facilitates the inquiries necessary to decide those issues, while deferential review avoids them. Courts cannot and should not avoid those responsibilities by deferring to "qualified" experts.

III. ACTIVE REVIEW OF SCIENTIFIC EVIDENCE

A. Active Review and the Rules of Evidence

The active review contemplated by this article and being conducted by some courts is a process in which the court conducts two inquiries. First, the court examines the evidentiary basis and reasoning of scientific opinion testimony and determines whether there is a rational basis for the opinion. The evidentiary basis of the opinion, as well as the expert's reasoning, can be probed by the proponent of the testimony, the opponent, or the court,[71] and will often be assisted by the defendants' experts.

The second inquiry focuses on the sufficiency of the admissible evidence to meet the plaintiff's burden of proof. This inquiry goes to the reliability or accuracy of the evidence and requires that the plaintiff present admissible evidence from which a reasonable juror could find that it is more probable than not that the defendant caused the plaintiff's

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analysis. *See infra* notes 310-14 and accompanying text; *see also* Black, *supra* note 15, at 674-76.

69. *See, e.g., In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. at 1250.

70. FED. R. EVID. 104 requires the court to determine questions of admissibility of evidence. *See, e.g.,* Eggar v. Burlington N.R.R., No. CV89-159-BLG-JFB, 1991 U.S. Dist. LEXIS 19240 (D. Mont. Dec. 18, 1991). Generally, the proponent of evidence must demonstrate by a preponderance of the evidence that the evidence in question is admissible. *In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp at 1239. Under FED. R. CIV. P. 50, 56, the court must determine the sufficiency of the evidence on a motion for summary judgment, a motion for a directed verdict, or a motion for judgment notwithstanding the verdict. Generally the standard for granting any of the foregoing (for defendant) is that no reasonable juror could find or have found for the plaintiff. *See, e.g.,* Renaud v. Martin Marietta Corp., 749 F. Supp. 1545, 1555 (D. Colo. 1990) (granting summary judgment to defendants), *aff'd,* 972 F.2d 304 (10th Cir. 1992).

71. FED. R. EVID. 705 provides: "The expert may testify in terms of opinion or inference and give his reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination."

As a practical matter, the court may have to do some translation of the language of the scientific field or of legal expressions into commonly understood terms. The court may also be guided by court-appointed experts who serve as witnesses or advisors. For an example of court-appointed experts serving as advisors to the judge, see *Renaud,* 749 F. Supp. 1545.

disease or injury. The same tools used to probe the underlying reasoning of the evidence can be used to inquire into its accuracy, but the question of whether the evidence is sufficiently accurate to satisfy legal standards is, of course, a legal question.

It is important to note that active review is not strict scrutiny.[72] The plaintiff need not show that her evidence is stronger than the defendant's or that it meets some high level of certainty. The plaintiff's scientific evidence need only be such that a rational factfinder could conclude from the testimony that it is more likely than not that the defendant caused the plaintiff's injury.[73] Only when the factual basis and reasoning underlying the expert's opinion on causation do not meet that minimum level of rationality and accuracy should the evidence be excluded.

Active review is not tied to any particular formulation of the standards for admissibility of expert testimony. It is, however, more easily related to the "reliability" determination embraced by a number of courts[74] than it is to the general acceptance rule of *United States v. Frye*.[75] The *Frye* rule forecloses the occasion for the court to examine the reasoning underlying the expert's method; however, it leaves questions such as the applicability of a generally accepted method to a particular case, the way in which a generally accepted method was carried out in a particular case,[76] and the sufficiency of the evidence to be addressed under other criteria. Thus, even if the United States Supreme Court upholds the application of the *Frye* rule in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[77] it will not eliminate the need for courts to actively review scientific expert testimony.[78]

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72. *But see, e.g.*, Peter A. Bell, *Strict Scrutiny of Scientific Evidence: A Bad Idea Whose Time Has Come*, Toxics L. Rep. (BNA) 1014 (1992). A more apt comparison would be to the "hard look" doctrine of administrative law, that is, the view articulated by Judge Leventhal that courts reviewing the decisions of a technical agency, such as the Environmental Protection Agency, should review the evidence on which the agency's decision is based to determine "whether the agency decision was rational and based on consideration of the relevant factors." Ethyl Corp. v. EPA, 541 F.2d 1, 34-36 (D.C. Cir.) (en banc), *cert. denied*, 426 U.S. 941 (1976). Judge Leventhal's views are not without detractors. *See id.* at 66-67 (Bazelon, C.J.). A non-technical, lay jury's decisions would seem to justify greater scrutiny than those of a regulatory agency with technical expertise.

73. *See, e.g., Renaud*, 749 F. Supp. 1545.

74. *See supra* notes 59-60.

75. *See supra* note 55.

76. *Cf., e.g.*, United States v. Jacobetz, 955 F.2d 787 (2d Cir. 1992) (the value of DNA testing depends on whether accepted protocols were followed in the specific case), *cert. denied*, 113 S. Ct. 104 (1992).

77. 951 F.2d 1129 (9th Cir. 1991), *cert. granted*, 113 S. Ct. 320 (1992).

78. The *Frye* rule at least creates a threshold for evaluation of the evidence that may serve to curb courts' tendencies to uncritically admit all arguably relevant evidence. The reliability standard nonetheless can serve an appropriate screening function if the court actually conducts a reliability analysis.

B. Active Review and Scientific Reasoning

One of the factors that seems to dissuade courts from scrutinizing scientific evidence more carefully is the belief that the differences between scientific and legal inquiries into causation are such that courts are poorly equipped to examine and evaluate science.[79] Actually, in determining whether there is a link between an event and a later harm, law and science use identical reasoning processes. Differences between scientific and legal institutions, goals and policies, however, obscure that commonality.

Judge Markey has succinctly stated an essential distinction between science and technology on the one hand, and law on the other:

> The differences between the judicial and scientific-technological processes are profound and pervasive. Failure to recognize that difference has led to judicial expressions of frustration and an unfortunate tendency to rest judicial decisions on current, often transient, "truths" and "facts" of science and technology. The purpose of science is to learn physical facts. The purpose and function of technology is to provide a means of using that learning. All that is important and necessary, but that's all it is—learning and using physical facts.
>
> The purpose and function of law is to resolve disputes and to facilitate a structure for the organization of a just society—in a word, to provide justice.[80]

As Markey suggests, science and law do differ in important ways. The culture, institutions and processes by which scientific knowledge is developed and refined are very different from those of law.[81] The development of scientific knowledge involves observation, hypothesis

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79. *See, e.g.*, Ferebee v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). The *Ferebee* court stated:

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

Id. at 1534.

80. Markey, *supra* note 42, at 210, *quoted in* Rubanick v. Witco Chem. Corp., 593 A.2d 733, 741 (N.J. 1991).

81. *See* Sheila Jasanoff, *What Judges Should Know About the Sociology of Science*, 32 JURIMETRICS J. 345 (1992); David Kaye, *Proof in Law and Science*, 32 JURIMETRICS J. 313, 317-18 (1992). The discomfort many scientist-experts experience in the adversarial setting of legal adjudication is largely due to scientists' perception that the law requires unequivocal statements on matters that are not clear cut from the scientist's perspective. Further, they are uncomfortable with the legal system's insistence on decisions, often before adequate evidence is available from a scientific perspective. For further discussion of the differences between the processes of legal and scientific inquiry, see Huber, *supra* note 15, at 739-42 (1992).

building, testing, generalizing, and consensus building.[82] Legal factfinding, on the other hand, is adversarial, confrontational, and directed toward a definitive result in the case at hand. Concern for consistency from case to case plays a lesser role in law[83] than in science.[84]

Unfortunately, these institutional and methodological differences obscure the reality that factfinding, that is, science in its broadest sense, is a necessary part of legal decisionmaking. Legal decisionmaking has additional policy components beyond the purely factual, so that it may attach different consequences to the same facts than would a scientist. Thus, the starting point for the analysis of the relationship between science and law on the issue of causation is a delineation of the factual and nonfactual components of legal concepts of cause.

To be sure, causation issues in tort law have nonfactual, policy-laden elements, as exemplified by the legal concept of proximate cause.[85] All tort theories include some notion of "cause-in-fact" as a prerequisite to liability,[86] however, and where cause-in-fact is concerned, science and law are attempting to answer the same questions. Further, law, like science, accepts only rational or reasoned findings of fact.[87] Most importantly, scientific and legal factfinding employ the same logic.[88]

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82. *See* Black, *supra* note 15, at 615-27.

83. In Wells v. Ortho Pharmaceutical Corp., 615 F. Supp. 262 (D. Ga. 1985), *aff'd in part, modified on other grounds*, 788 F.2d 741 (11th Cir.) (modifying damage award), *cert. denied*, 479 U.S. 950 (1986), the court held that plaintiff had proved that her daughter's birth defects were caused by the mother's prenatal use of a spermicide, despite FDA approval and scientific consensus that spermicides do not cause birth defects. *See id.* at 266. *But see* Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 315 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990). In *Brock*, the court expressed the hope that its ruling would have "a precedential effect on other cases pending in this circuit which allege Bendectin as the cause of birth defects." *Id.* at 315.

84. That is not to say that science is fixed and unchangeable. Scientific knowledge is always open to revision as new information comes to light that is inconsistent with previously understanding. The point, however, is that scientific reasoning requires that a scientific explanation accommodate and be consistent with all the available data at any point in time.

85. The concept of proximate cause is generally recognized as encompassing policy questions of how closely the defendant's tortious conduct must be related to the plaintiff's injury for the defendant to be held liable. *See, e.g.*, Richard W. Wright, *Responsibility, Risk, Probability, Causation, Naked Statistics and Proof: Pruning the Bramble Bush by Clarifying the Concepts*, 73 IOWA L. REV. 1001, 1011-12 (1988). Viewed in that light, the proximate cause requirement is a limitation on liability where defendant's conduct was the actual cause of plaintiff's injury. *Id.*

86. *See id.* Of course, the way in which the factual question is framed, as well as the burden of proof and evidentiary standards has policy overtones. *See* Eggen, *supra* note 35, at 899-904 (suggesting shift of burden of proving causation); Nancy L. Firak, *The Developing Policy Characteristics of Cause-in-Fact: Alternative Forms of Liability, Epidemiologic Proof and Trans-Scientific Issues*, 63 TEMP. L. REV. 311, 313 (1990) (arguing that courts' acceptance of epidemiologic evidence is a policy choice rather than a factual conclusion).

87. *See* Wright, *supra* note 85, at 1011-12; *see also In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1250 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487

Much of the early commentary about the differences between science and law in toxic torts concerned courts' discomfort with statistical evidence of causation. Commentators have attributed that discomfort in part to courts' preferences for mechanistic causal explanations and their reluctance to rely heavily or entirely on statistical evidence.[89] Courts and lay persons typically think about causal issues in terms of *how* things happen and statistical evidence does not explain how events occur.[90]

When mechanistic thinking about cause is extended to the area of toxic substance disease causation, it immediately encounters a large, perhaps insurmountable, stumbling block. Scientists know very little about how, in a mechanistic sense, toxic substances cause diseases such as

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U.S. 1234 (1988). The ubiquitous legal requirement that there exist a rational or reasonable basis for findings of fact evidences the underlying assumption that reasoning and logic must connect evidence to conclusions.

88. David Kaye has demonstrated that science and law use the same logical rules in proving facts. *See* Kaye, *supra* note 81. He concludes: "[W]hen it comes to proving facts, the logic of law and that of science are one and the same. At an abstract level, the rules of inference can be given the same formal representation." *Id.* at 317; *see also* Lee Loevinger, *Standards of Proof in Science and Law*, 32 JURIMETRICS J. 323, 328 (1992).

In regard to the role of social science in overturning *Plessy v. Ferguson*, Kenneth B. Clark has stated:

> The development of science as an approach to the determination of truth involved the development of methods for the control of errors in human observation, judgment, biases, and vested interests. These were the factors which seemed to have distorted man's concept of, or blocked his contact with, the "truth" or "facts" of experience. When they are operative, man's "common knowledge" becomes inconsistent with "scientific knowledge." When they are controlled or for some other reason non-operative, "common knowledge" and "scientific knowledge" are coincident—both reflecting the nature of reality, truth, or facts, as these are knowable to the human senses and intelligence.
>
> Science is essentially a method of controlled observation and verification for the purpose of reducing human errors of observation, judgment, or logic. Science begins with observation and ends by testing its assumptions against experience. It is not a creation of another order of reality. In a very basic sense there cannot be a "legal fact" or a "fact of common knowledge" which is not at the same time a "scientific fact." Whenever this appears to be true, one or the other type of "fact" is not a fact.

Kenneth B. Clark, *The Desegregation Cases: Criticism of the Social Scientist's Role*, 5 VILL. L. REV. 224, 233 (1959).

89. *See e.g.*, Brennan, *supra* note 15, at 478-91. Brennan refers to mechanistic conceptions of cause as "corpuscularianism," after the writings of various philosophers of science. *See id.* at 478-79.

90. The understanding of how a cause produces an effect makes us more comfortable with the conclusion that causation occurred. Richard Wright puts it this way:

> Usually, the issue [of proving causation] is what has happened—including how it happened and who did it—although sometimes the issue is what is expected to happen—for example, the expected reduction in future income as an element of damages. That is, proof generally involves either causal explanation or causal prediction.

Wright, *supra* note 86, at 1049.

cancer or injuries such as birth defects.[91] Nonetheless, they may know a considerable amount about *whether* toxic substances cause disease or injury through inferences drawn from statistical associations and other indirect means.[92] Thus, the shift in thinking required for courts to come to grips with current scientific knowledge had more to do with abandoning a felt need for an explanatory process that increases comfort with the causal inference than it did with redefining causation.

Courts' discomfort with statistical evidence has gone beyond the absence of mechanistic explanations, however.[93] Statistical evidence by definition provides information only about the incidence of disease in groups. Where there are other possible causes of disease, statistical evidence cannot determine which individuals' diseases within the exposed group were caused by background or other factors.[94] It can only

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91. Brennan, *supra* note 25, at 20-25 (discussing scientific evidence of cancer causation).

92. *Id.*

93. *See* Black & Lilienfeld, *supra* note 37, at 744-50; Brennan, *supra* note 15, at 483-93. Brennan states that courts' refusal to consider and accept statistical evidence reflects and is consistent with courts' traditional reliance on mechanistic causal explanations. *See* Brennan, *id.* at 491-92.

94. Extensive or complete reliance on epidemiologic proof and other statistical evidence is not without its detractors. *See, e.g.*, Michael Dore, *A Commentary on the Use of Epidemiologic Evidence in Demonstrating Cause-in-Fact*, 7 HARV. ENVTL. L. REV. 429 (1983); Wright, *supra* note 86, at 1049-67 (arguing that particularistic evidence is required to prove actual causation). Dore reiterates the commonly held view that epidemiologic evidence is proof not of actual, individual causation, but only of risk. *See* Dore, *supra*, at 435. Regarding the use of epidemiology in proving risk (apparently meant as the ability of a substance to cause harm), Dore states:

> Within the limitations just discussed, epidemiologic evidence can demonstrate the relative level of risk to which the defendant's activities exposed the members of the plaintiff's group. This risk, of course, does relate to the individual plaintiff. Courts that fail to distinguish the issue of risk from that of actual causation may accordingly, but erroneously, permit the evidence of risk to establish causation. Epidemiologists do not design their studies to resolve issues of individual biological causation, however, and the courts must strictly limit the use of such studies for this purpose.
>
> The limitations on epidemiology's ability to prove individual causation stem from its general and statistical nature. Epidemiologic studies are general in that they deal with sources of disease in groups of people rather than particular individuals. Being statistical, they quantify the probabilities, or risks, that members of a group will contract certain diseases under certain conditions. The only individual cause-and-effect relationship that epidemiologic evidence can show is that the defendant's conduct increased the plaintiff's risk of injury to some statistically measurable extent. *It cannot answer the critical question whether the defendant's conduct actually injured the plaintiff.*

Id. at 436 (citations omitted). Dore and other detractors of statistical evidence frame the question incorrectly, however. The issue in toxic torts is whether there is evidence from which an inference can be made that it is more probable than not that the exposure caused the plaintiff's disease. As others have pointed out, the statistical evidence provided by epidemiology is probative of that issue. *See* Black & Lilienfeld, *supra* note 37, at 764-69 (combining relative risk with more-probable-than-not standard of proof); Khristina L. Hall

provide an estimate of the likelihood that an individual's disease was caused by the toxic substance in question.[95] Thus, courts' concerns are not unreasonable. The more likely than not standard of proof, however, implicitly contemplates the marshaling of facts that ultimately prove liability in terms of probabilities.

Uncomfortable with factual indeterminacy, some courts rejected statistical evidence entirely, demanding evidence that is particular to the plaintiff.[96] Other courts have accepted statistical evidence on issues such as whether a toxic substance is capable of causing harm, but not on the question of whether it caused the plaintiff's harm.[97] A number of recent cases, however, have recognized the necessarily statistical nature of proof at all levels in toxic torts, and accepted statistical evidence as probative of individual causation, at least where there is evidence indicating a greater than 50% likelihood that the toxic substance caused the plaintiff's disease.[98] A number of recent decisions evidence a sophisticated understanding of epidemiologic evidence and its relation to legal standards of proof.[99]

The remaining areas where science seems to fit poorly with legal problems are largely the result of failure to distinguish legal standards of proof from factual issues. Courts are concerned that they must decide cases based on the information available, which may not be complete enough to satisfy the requirements of a particular scientific discipline.[100] Some courts perceive scientists as generally requiring higher levels of certainty than does the law.[101] That perception may be correct in some instances, particularly in areas such as epidemiology, where standard

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& Ellen K. Silbergeld, *Reappraising Epidemiology: A Response to Mr. Dore*, 7 HARV. ENVTL. L. REV. 441, 445-46 (1983). Indeed, signature diseases, which are usually not perceived as presenting difficult individual causation issues, are simply cases in which the statistical evidence is very persuasive because the background incidence of disease is very low compared to the incidence in the exposed population.

95. *See supra* notes 94 and accompanying text.

96. *See* Brennan, *supra* note 15, at 492 & nn.114-15.

97. *See, e.g.*, Landrigan v. Celotex Corp., 605 A.2d 1079 (N.J. 1992) (reversing the trial court's rejection of opinion testimony on individual causation based on epidemiology).

98. *See, e.g., id.* at 1087.

99. *See, e.g.*, DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 946-56 (3d Cir. 1990) (discussing the statistical significance of epidemiologic data); *Landrigan*, 605 A.2d at 1085-87 (discussing the significance of relative risk and attributable fraction).

100. *See, e.g.*, Ferebee v. Chevron Chem. Corp., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). The *Ferebee* court held that a treating physician could testify to his opinion that a cause and effect relationship existed between the insecticide paraquat and Ferebee's pulmonary fibrosis even if such a relationship had not been "clearly established" by animal or epidemiologic studies. *Id.* at 1535.

101. In Rubanick v. Witco Chem. Corp., 593 A.2d 733, 737, 740-41 (N.J. 1991), the New Jersey Supreme Court made several references to the "extraordinarily high level of proof" required by the scientific method. Defendant's witness apparently played into that concern, however unwittingly. *See id.* at 737.

protocols for statistical analysis of relative risk data typically require a 95% level of certainty that an observed increased in risk is not due to chance.[102] Scientists do not require a high degree of certainty for all purposes, however. Risk assessment for purposes of regulation is based on highly uncertain risk estimates. Additionally, scientists often use highly tenuous or uncertain assumptions in making decisions about further research.[103]

The issue of how much uncertainty is acceptable is a legal requirement to be applied to the evidence once the uncertainty attending the scientific evidence is established.[104] Where the law requires the plaintiff to prove her case by a preponderance of the evidence, current standards permit the plaintiff to win if sufficient evidence is available, but not prevail if it is not available.[105] Scientific evidence can be evaluated against those standards, irrespective of whether the scientific discipline would be satisfied or not with the available level of certainty.[106] Moreover, the fact that scientists may require a different level of certainty is not a good reason to dispense with science's requirement of a reasoned analysis, a requirement common to law and science. Unfortunately, some courts throw the baby out with the bathwater by rejecting scientific reasoning altogether when they perceive scientists' requirements for certainty to be too stringent.[107]

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102. Black & Lilienfeld, *supra* note 37, at 757 n.104; *see infra* notes 364-67 and accompanying text; *see also DeLuca*, 911 F.2d at 946-49 (discussing statistical significance in epidemiology).

103. For example, as discussed in Wells v. Ortho Pharmaceutical Corp., 615 F. Supp. 262 (D. Ga. 1985), *aff'd in part, modified on other grounds*, 788 F.2d 741 (11th Cir.) (modifying damages), *cert. denied*, 479 U.S. 950 (1986), the "Oeschli study" raised suspicions about the possibility of an association between spermicides and birth defects and recommended further study. *Id.* at 284. Further studies with greater statistical power failed to confirm that suspicion. *See id.*

104. *See* Black, *supra* note 15, at 600 (discussing reliability as a legal question).

105. From that perspective, science and law seem to have parallel requirements because each refuses to reach an affirmative conclusion that causation exists until an acceptable level of certainty is attained, even though the law and the scientific discipline may require different levels of certainty. The relationship between legal and scientific notions of sufficiency of proof is perhaps less clear, however, than is the identity of the logic employed by each. *See* David Kaye, *On* Standards *and* Sociology, 32 JURIMETRICS J. 535 (1992); Lee Loevinger, *On* Logic *and* Sociology, 32 JURIMETRICS J. 527 (1992). *Compare* Kaye, *supra* note 81, *with* Loevinger, *supra* note 88.

106. That is not to say that scientists' perceptions of the appropriate level of certainty should be ignored. Requirements such as epidemiologists' practice of requiring a 95% confidence level often have their roots in years of experience in the discipline. With epidemiologic studies in particular, there may be undetected systematic bias in selection of the comparison groups, including the possibility of undetected confounding factors, that are not taken into account in the statistical analysis. *See* ROTHMAN, *supra* note 44, at 89-96; Black & Lilienfeld, *supra* note 37, at 737-38; *infra* text accompanying notes 346-49.

107. *See, e.g.*, Rubanick v. Witco Chem. Corp., 593 A.2d 733 (N.J. 1991), *discussed infra* notes 287-300 and accompanying text.

Courts can and should evaluate the underlying reasoning of scientific evidence and measure its reliability or uncertainty against legal standards of sufficiency to meet the applicable burden of proof. The following part of this article attempts to facilitate that process by explicating the bases on which courts can recognize and reject invalid or unreliable evidence, matters on which the differences between science and law are a matter of degree, not kind. Thus, courts need not fear that delving into science and technology will be entirely a foray into alien territory.

IV. ACTIVE REVIEW OF CAUSATION EVIDENCE IN TOXIC TORTS

A. Validity, Reliability, and the Determination of Probative Value

Whether courts operate under the *Frye* rule, the "reliability" standard of *United States v. Downing*,[108] or some other formulation of the rules governing scientific expert testimony, the question courts must answer when they evaluate scientific evidence is, "How probative is it?"[109] That question includes two subissues, however: validity and reliability.[110] Validity is the issue of whether the evidence is capable of producing the kind of information sought; thus, it is essentially equivalent to the concept of relevance as used in the rules of evidence.[111] Reliability connotes the likelihood of a correct or accurate result,[112] and thus encompasses notions of certainty or accuracy.[113] Reliability is

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108. 753 F.2d 1224 (3d Cir. 1985).

109. So framed, that question corresponds to the determination of "reliability" under United States v. Downing. *See supra* notes 59-63 and accompanying text.

110. *See* Black, *supra* note 15, at 599-600 (discussing validity as part of the reliability determination).

111. FED. R. EVID. 401.

112. *See supra* note 110.

113. This Article thus adopts and expands on the analytical framework proposed by Black, although it uses the terms validity and reliability in a slightly different way. *See generally* Black, *supra* note 15.

Black defines validity as "that which results from sound and cogent reasoning," and reliability as meaning "that a successful outcome, or correct answer, is sufficiently probable for a given situation." *Id.* at 599-600. Thus, he frames validity as a scientific question, and reliability as a legal one. *Id.* at 600. Validity is to be determined largely by reference to widespread acceptance in the scientific community of the underlying reasoning. *Id.* at 637-38. Black also recognizes, however, that some aspects of the validity analysis relate to the specifics of a particular case that must be examined apart from the test of general acceptance. *See id.* at 657-58 (discussing *Downing* court's evaluation on remand of the applicability of research on eyewitness identification to the facts at hand).

As defined by Black and as used herein, validity is a subissue of reliability, rather than a separate and independent factor, since invalid reasoning or methodology cannot

therefore the ultimate indicator of the probative value and sufficiency of evidence, either alone or in combination with other evidence, to meet the more probable than not standard of proof.

Consider, for example, a diagnostic blood test for a viral blood disease. Without the blood test, the disease can be diagnosed only by elaborate procedures. A simple test is desired for screening large numbers of blood samples for the presence of the virus. A virologist might speculate about any number of parameters that might be indicative of the presence of the virus. None of the possible indicators could be used as a diagnostic test, however, until validated by testing that demonstrates a correspondence between the indicator (a "positive" test) and the presence of the virus. This example illustrates the more general principle that where the physical connections between observed and inferred facts are hidden from direct observation, it is necessary for the inferred connection (e.g., between the indicator and the virus) to be validated through trials or tests that independently measure the properties or characteristics that are ostensibly connected.[114]

A valid method may nonetheless be insufficiently reliable for evidentiary purposes; that is, the method may be incapable of producing the desired information to an acceptable level of certainty. Using again the example of a test for an asymptomatic virus, the test might have a high rate of false positives or false negatives, or both. Thus, although persons who are test positive are more likely than those who test negative to actually have the virus in their blood, the test may be too inaccurate or unreliable for the purpose for which it is administered.[115] Similarly, if the question of whether someone is infected with the virus were a factual

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produce reliable or accurate results. *See id.* at 599-606, 613. Reliability is the criterion that courts tend to apply to expert scientific evidence; thus, the proposed analysis fits within recognized criteria for evaluating scientific evidence. *See supra* notes 59-60 and accompanying text.

The definitional structure used herein departs, however, from the usage of the terms validity and reliability in social science research. In social science disciplines, reliability describes the reproducibility of the results and validity describes the degree to which the phenomenon measured corresponds to the phenomenon sought to be measured. Thus, this Article's use of reliability to encompass the accuracy as well as the reproducibility of an outcome encompasses some issues that would be characterized as validity issues under the social science rubric.

114. In toxic torts, validity issues are present when a physician or other expert witness testifies on causation based on patient examination even though there is no clinical basis for linking individual cases to a particular causative agent. *See infra* text accompanying notes 197-205.

115. If, for example, the test were used to determine whether donated blood is safe for transfusions, a significant rate of false negatives would be of much greater concern than a correspondingly high rate of false positives.

question in a legal setting, our hypothetical test might be insufficiently reliable to satisfy the legal standard of proof.[116]

Validity or reliability questions may arise when methodology that has proved valid and reliable is applied in new circumstances. Invalid application of valid methodology may result from extending a method or line of reasoning to purposes for which it has not been validated.[117] In toxic torts, this question arises in connection with whether the conclusions derived from toxicological research on animals or single-celled organisms are applicable to humans.[118]

Uncertainty or reliability questions may also result from the improper application of valid and reliable methodology. Failure to properly calibrate an instrument such as a breathalyzer, or other concerns related to how a method is applied in a particular case, may increase the likelihood of erroneous results.[119] Assume, for example, that in the hypothetical virus test, the incidence of false negatives increases with the length of time that the patient's blood samples are stored before the laboratory test is run. The inferences drawn from a test run by a laboratory that stores its blood samples longer that the optimum time for the test would be subject to a greater variation and uncertainty than results from a laboratory that runs its tests promptly.

A subset of questions regarding "reliability as applied," particularly where the methodology involves calculations from raw data, concerns the quality and quantity of the underlying data. In toxic torts, the data on which estimates of exposure to a toxic substance are based are often sketchy or subject to large uncertainties. Those uncertainties make the inferences of causation that depend on the exposure data similarly uncertain and unreliable.

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116. If the question whether someone is infected with a virus were part of the prosecution's proof in a criminal action, that fact would have to be proven beyond a reasonable doubt, so that any significant rate of false positives would likely render it "unreliable" for that purpose. Proof in a civil action would have to satisfy a more probable than not standard, so that a somewhat higher level of false positives, possibly up to 49%, could be tolerated. Courts sometimes refuse to admit evidence that nominally satisfies the applicable standard of proof, however.

117. The issue of the generalizability of a study is characterized as one of external validity. *See* ROTHMAN, *supra* note 44, at 95-96 (epidemiologic studies).

118. *See, e.g., In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1273 (E.D.N.Y. 1985) (questioning the use of human epidemiologic studies of workplace dioxin exposures and animal studies as evidence of effects in Vietnam veterans), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988).

119. *See* MCCORMICK ON EVIDENCE § 209, at 513 (Edward W. Clearly ed., 3d ed. 1972) (discussing factual predicate for admitting chemical testing for alcohol intoxication). Courts differ, however, in their approach to whether the manner in which a method is applied goes to the weight of the evidence rather than its admissibility, and is therefore a jury question. *See, e.g.*, United States v. Jakobetz, 955 F.2d 786 (2d Cir.) (DNA testing), *cert. denied*, 113 S. Ct. 104 (1992).

B. Validity and Reliability of Causation Evidence in Toxic Torts

Analysis of the kinds of evidence at issue in the typical toxic torts case illuminates many of the problems with such evidence that tend to be obscured when cases are considered as a whole. The following discussion is intended to suggest some ways of looking at such evidence to distinguish probative evidence from junk science; thus, the discussion deals separately with the subissues of the ability of the toxic substance to cause disease (general causation), exposure, and the causation of the plaintiff's disease (individual causation). It would be well to keep in mind, however, that the ultimate question on causation is whether the evidence allows a reasoned conclusion that exposure to the toxic substance in question, rather that other known or unknown factors that also cause such disease, caused the plaintiff's condition.

As noted previously, the characteristics of toxic tort cases impose limitations on the ability to establish causal connections between exposure and disease. The latency periods typical of toxic tort injuries, the absence in most cases of a unique signature injury associated with a toxic substance, the fact that injury does not occur in every instance of exposure, and the absence of clinical indicators that discriminate among causes of a particular individual's disease all tend to obscure toxic injury causation.[120] In simple terms, the typical toxic tort case looks something like this: The plaintiff believes she has been exposed to a toxic chemical. She has a disease that is commonplace, or at least not unknown, in the general population. The current progress of the disease bears no relation to the continuation of exposure, and the exposure may have long since terminated. There is no diagnostic or clinical test that can determine what caused her disease.

How can such a plaintiff prove that a toxic substance caused her disease? Because of the absence of clinical indicia of cause, the plaintiff must always make out her case indirectly. First, she needs evidence that the substance can cause the condition from which she suffers and of the circumstances under which disease causation is reasonably likely to occur. The coincidence of exposure and disease in the same individual, while necessary, can never be sufficient to prove the capability of the substance to cause disease. Similar problems attend the use of anecdotal case reports or evidence of clusters of disease that have not been subjected to statistical analysis because a certain amount of coincidence and toxic chemical exposure or even clustering of a disease can occur as the result of random chance.[121]

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120. *See supra* notes 43-49 and accompanying text.

121. Chance may lead to disease clusters rather than disease uniformly distributed throughout a large population. Anecdotal reports and clusters of disease are important in