

Trans-Science in Torts

Wendy E. Wagner

Forty years after science established that asbestos was hazardous to humans,¹ the first plaintiff recovered damages against an asbestos manufacturer. This delay resulted from the inability of science to meet the legal, "more probable than not" causation standards that require that the effect of the hazard be quantified on humans. To determine whether exposure to a substance is a statistically significant factor in the cause of a disease, epidemiologists must compare a significant number of subjects exposed to the substance to unexposed populations.² Since the first successful epidemiological study was completed,³ over 20,000 claims have been filed nationwide against manufacturers and installers of asbestos.⁴

This pattern of delay is common to the toxic tort field.⁵ In a variety of other cases involving such injuries as adenocarcinoma,⁶ pelvic inflam-

1. Cases of asbestosis in asbestos textile workers had been reported as early as 1924, *see* Cooke, *Fibrosis of the Lungs Due to the Inhalation of Asbestos Dust*, 2 BRIT. MED. J. 147 (1924). Thereafter, numerous other studies indicated the significant peril of exposure to asbestos in asbestos textile factories. For a general discussion of these studies, *see* *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1083-84 (5th Cir. 1973) (outlining scientific history of study of effects of asbestos on health).

2. Thus, quantification of the effects of a substance on human health is inherently retrospective. Epidemiological studies conducted prospectively exist only insofar as test individuals are free of the disease at the inception of the study (e.g., cohort studies)—a percentage of individuals must still be exposed to the hazard in question before the effects of the substance are known. *See* J. KELSEY, W. THOMPSON & A. EVANS, *METHODS IN OBSERVATIONAL EPIDEMIOLOGY* 8-9 (1986) (discussion of different research techniques in epidemiology, all of which are ultimately retrospective).

3. Selikoff and his colleagues adduced a definitive quantitative assessment of the risk of contracting asbestosis following exposure to asbestos in their seminal 1965 study. Selikoff, Churg & Hammond, *The Occurrence of Asbestosis Among Industrial Insulation Workers*, 132 ANNALS N. Y. ACAD. SCI. 139 (1965). The authors examined 1,522 members of an insulation workers union in the New York/New Jersey area and discovered that almost half of those examined exhibited signs of pulmonary asbestosis. In the subgroup of workers employed over 40 years, abnormalities were detected in over 90%.

4. By mid-1982, 11,000 health-related cases brought by 15,500 plaintiffs were pending against Johns-Manville Corporation alone. Thereafter, suits were filed at a rate of about 425 cases per month. W. Lundquist, *Innovations in Mass Tort Litigation*, Paper presented at the Meeting of the American Association of Law & Science, Section on Torts (Jan. 23, 1984) (on file with author).

5. Toxic torts cases are generally defined as product liability suits which arise from exposure to substances that pose a substantial risk of death or impairment either immediately or over a period of time. These cases differ from more traditional strict liability cases: often more persons are exposed to a product than actually buy it, which causes case management problems for determining and organizing plaintiffs and defendants; a longer lag time usually occurs between injury and exposure; and there is greater need for expertise and scientific studies to prove a defect in toxic substances. McGovern, *Management of Multiparty Toxic Tort Litigation: Case Law and Trends Affecting Case Management*, 19 FORUM 1 (1983).

6. *See, e.g., Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924 (1980) (plaintiff daughters of mothers who took diethylstilbesterol (DES) brought suit against manufacturers of synthetic

matory disease,⁷ toxic shock syndrome,⁸ and Guillain-Barré Syndrome,⁹ the general population was exposed to known health hazards, but recovery was granted only after a statistically significant number of deaths and injuries were incurred, allowing experts to quantify the hazard.¹⁰ This Note discusses the inherent problems with a causation standard that requires that the hazardous nature of a substance be quantified in the general population before granting recovery.¹¹ Scientific quantification requires both that an epidemiological study be conducted, a highly expensive and time-consuming undertaking,¹² and that the study be successful in distinguishing injuries caused by the product from those induced by the general environment.¹³ These scientific barriers not only ensure that very few sub-

estrogen products); *Abel v. Eli Lilly & Co.*, 418 Mich. 311, 343 N.W.2d 164 (1984) (same).

7. *See, e.g.*, *Coursen v. A.H. Robins Co.*, 764 F.2d 1329 (9th Cir. 1985) (users of contraceptive intrauterine device brought suit against manufacturer for contraction of pelvic inflammatory disease).

8. *See, e.g.*, *Kehm v. Proctor & Gamble Mfr.*, 724 F.2d 613 (8th Cir. 1983) (survivors of woman who died of toxic shock syndrome brought product liability action against manufacturer of tampons).

9. *See, e.g.*, *In re Swine Flu Immunization Prods. Liab. Litig. v. United States*, 533 F. Supp. 567 (D. Colo. 1980) (plaintiff brought suit under Federal Tort Claims Act for injuries arising from Swine Flu inoculation).

10. In each of these cases, the court demanded epidemiological evidence to satisfy the general causation requirement. Evidence only that the substance was risky (e.g., carcinogenic), based on animal and other non-human research, was inadequate.

11. Although there are many other serious problems inherent in toxic tort suits, such as case management, *see, e.g.*, Note, *Class Certification in Mass Accident Cases Under Rule 23(b)(1)*, 96 HARV. L. REV. 1143 (1983), they are secondary to the overriding problem of scientific uncertainty and the absence of conclusive facts for any satisfactory decision in favor of either plaintiff's recovery or manufacturer's immunity. *See also infra* note 48 (distinguishing this Note's trans-scientific focus from other trans-scientific issues). In fact, once courts acknowledge this scientific uncertainty, the increased predictability of outcomes may make case management and financial planning easier.

The fundamental premise of this Note is that the legal system ignores hazards and other man-made risks which have not yet been studied thoroughly or analyzed statistically. The high improbability that the effects of an unsafe product will be quantified, in turn, considerably impedes deterrence. In contrast, Steve Gold, the author of Note, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376 (1986) [hereinafter Gold Note], indicates that the primary problem in toxic tort cases is the misuse of statistical evidence that is already well-established. This Note addresses toxic torts that are no longer trans-scientific, or are at least able to be quantified as to the magnitude of the hazard or risk. *See, e.g., id.* at 380 ("Toxic tort litigation, therefore, involves inferences on causation derived from group-based information [i.e., epidemiological studies] . . .").

12. *See, e.g.*, H. NORTHRUP, R. ROWAN & C. PERRY, *THE IMPACT OF OSHA: A STUDY OF THE EFFECTS OF THE OCCUPATIONAL SAFETY AND HEALTH ACT ON THREE KEY INDUSTRIES—AEROSPACE, CHEMICALS, AND TEXTILES* 232 (1978). For example, epidemiological data is available for only 14% of the more than 400 chemicals currently reviewed by the International Agency for Research on Cancer. *See* Althouse, Huff, Tomatis & Wilbourn, *An Evaluation of Chemicals and Industrial Processes Associated with Cancer in Humans Based on Human and Animal Data: IARC Monographs Volumes 1 to 20*, 40 CANCER RES. 1, 1-2 (1980).

13. In most cases there is no unique set of symptoms for diseases resulting from exposure to hazardous substances, and often the symptoms resemble those resulting from the natural aging process or common diseases. *See, e.g.*, J. KELSEY, W. THOMPSON & A. EVANS, *supra* note 2, at 12; Duce, *In Search of Adequate Compensation for Toxic Waste Injuries: Who and How To Sue*, 12 PEPPERDINE L. REV. 609, 620 (1985). Additionally, many diseases result from multifactorial etiology—several factors interact together to produce harm. *See, e.g.*, J. KELSEY, W. THOMPSON & A. EVANS, *supra* note 2, at 16 (discussing "effect modification" occurring when magnitude of cause and disease varies according to a third variable); Rodricks & Tardiff, *Conceptual Basis for Risk Assessment*, in ASSESS-

stances will be studied adequately to meet existing legal requirements,¹⁴ but also make it difficult, or even impossible, for a manufacturer to predict liability in the interim period after animal experimentation indicates that a substance is dangerous, but before the hazard is quantified on humans.¹⁵ In order to reincorporate deterrence into toxic tort cases¹⁶ and to provide a basis for determining liability in this scientifically uncertain interim period, the standard for liability must be revised.¹⁷

This Note proposes a causation standard that circumvents problems whose solutions are scientifically indeterminate by combining a qualitative showing of causation with proof that the manufacturer acted negligently in introducing an "abnormally dangerous" product. Qualitative evidence of a causal link would include proof of substantial exposure to the substance and injury consistent with that substance, rather than the present requirement that plaintiff prove with statistical certainty that causation was "more probable than not."¹⁸ Proof that the substance is "abnormally dangerous" would involve a finding that a manufacturer acted negligently in marketing a product when it "should have known" that the product

MENT AND MANAGEMENT OF CHEMICAL RISKS 3, 4 (J. Rodricks & R. Tardiff eds. 1984); Trauberman, *Statutory Reform of "Toxic Torts": Relieving Legal, Scientific, and Economic Burdens on the Chemical Victim*, 7 HARV. ENVTL. L. REV. 177, 199 (1983).

14. The FDA has set the "adequate level of research" for some chemicals through pretesting regulations. See, e.g., 21 C.F.R. § 314.50 (1985) (regulations governing pretesting of drugs under Food and Drug Act). However, only a small minority of chemicals presently in use have been subject to these tests or have been studied even minimally. STEERING COMM. ON IDENTIFICATION OF TOXIC AND POTENTIALLY TOXIC CHEM. FOR CONSIDERATION BY THE NAT'L TOXICOLOGY PROGRAM, NATIONAL ACADEMY OF SCIENCE, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES 10-12 (1984).

15. Although Congress has supplemented tort liability with statutory and regulatory controls on hazardous substances, these legislative remedies have proven largely ineffectual. First, statutory control of toxic substances is dispersed over a dozen statutes and regulated by five agencies. This piecemeal regulation produces inconsistent and inefficient results. Second, the small budgets of these agencies preclude effective regulation of a vast number of chemicals. Third, the regulatory agencies tend to operate from a set of static rules which do not promote technological innovation or adapt to improvements in research techniques. See Trauberman, *supra* note 13, at 203-05. Finally, many toxic substances simply fall between the statutory cracks and are not subject to direct regulation. See Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403, 1403 (1983).

16. See, e.g., Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 849, 855 (1984) ("[I]n contrast to sporadic accidents, which generally result from all-too-human individual lapses of attention, mass exposure torts are frequently products of the deliberate policies of businesses that tailor safety investments to profit margins. Such risk-taking policies should be especially amenable to control through threats of liability." (footnotes omitted)).

17. In developing the strict product liability doctrine, courts have tended to place less emphasis on determining the most equitable way to distribute losses among the parties, such as individualized rights and basic principles of fault and punishment, and instead have sought to identify the most expedient and efficient way to fulfill broader principles of societal well-being. This Note argues that the principles of strict products liability, which consider only proof that the product was defective and caused the injury, must be modified, and fundamental tort goals of deterring negligent or wrongful conduct should be given more prominence in determining liability in trans-scientific cases. See Hollenshead, *Historical Perspective on Product Liability Reform*, 1 J. PROD. LIAB. 75, 81 (1982).

18. See *infra* notes 43-51 and accompanying text.

posed a serious risk, although still unquantified, to human health. The jury would determine whether the manufacturer's marketing decision that the benefits of the product outweighed the costs to human health was reasonable.¹⁹ If a plaintiff satisfies both of these requirements—proof of a qualitative causal link and the distribution of an “unreasonably dangerous” product—then the burden will shift to defendant to prove that the product was safe, the hazards were not foreseeable, benefits outweighed potential costs at the time of marketing, or that the plaintiff was not exposed to substantial concentrations of the product.

I. THE PROBLEM IN TOXIC TORTS: TRANS-SCIENCE

At the heart of the problem presently confronted by the courts in toxic tort suits is the inability to determine causation quantitatively when trans-scientific issues²⁰ are involved—when questions asked of science, such as the statistically significant effects of a chemical on human health, cannot be answered at the time.²¹ For example, early quantification of the risk a chemical poses to human health is impossible because ethical policies preclude tests on a large number of humans.²² Instead, science is capable only of indicating that a substance is generally dangerous through studies on non-human subjects or accidental spills.²³ Thus, for many types of inju-

19. See *infra* notes 77–88 and accompanying text.

20. Alvin Weinberg, a radiation specialist at Oak Ridge Laboratory, first developed the notion of “trans-science”:

The point missed . . . is that the seemingly simple question ‘What is the effect on human health of very low levels of physical insult?’ can be stated in scientific terms; it can, so to speak, be asked of science, yet it cannot be answered by science. I have . . . proposed the name *trans-scientific* for such questions that seemingly are part of science yet in fact transcend science . . . [Even] any null experiment—that is, an experiment that shows no biological effect at low levels of insult—does not *prove* the insult is harmless, since a larger experiment might show effects. . . . I must stress that where low-level effects are concerned, there will always be a trans-scientific residue. To decide on standards when science can say neither yea nor nay requires some procedure other than the one usually used by scientists in resolving bona fide scientific questions.

Letters to the Editor, 174 *SCIENCE* 546–47 (1971) (letter from Alvin Weinberg); see also Weinberg, *Science and Trans-Science*, 10 *MINERVA* 209 (1972).

21. In this crystal ball question, the tools which would be necessary for an accurate prediction would include the ability to test hazardous substances on a large number of human subjects in carefully controlled circumstances over a long period of time. In the case of the effects of Agent Orange, for example, the definitive study would examine the effects of the herbicide on large populations at various low concentrations over a period of twenty to fifty years. In addition, an epidemiologist would have to isolate control populations identical to the exposed populations to eliminate the effects of all other variables. Resulting statistics might indicate correlations between exposure to Agent Orange and resultant injuries.

22. See C. FRIED, *MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY* (1974); NATIONAL ACADEMY OF SCIENCES, *EXPERIMENTS AND RESEARCH WITH HUMANS: VALUES IN CONFLICT* (1975); R. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* (1981); WORLD HEALTH ORGANIZATION, *PRINCIPLES AND METHODS FOR EVALUATING THE TOXICITY OF CHEMICALS, PART I* 41–43 (1978).

23. See W. ROWE, *EVALUATION METHODS FOR ENVIRONMENTAL STANDARDS* 26–29 (1983) (discussing limited data bases for determining effects of toxic substances on human health). Most

ries, several decades may pass before harm manifests following low, but continuous exposure to the hazardous substance.²⁴ In the following section, trans-science will be defined and its impact on the judicial system examined. Section II will investigate the legal bases for the present inadequacy of the courts to adjudicate trans-scientific issues. Section III will outline a proposal for reform that attempts to mold the judicial system to adapt to the unique characteristics of trans-science.

A. *The Source of the Problem*

Unlike the traditional scientific process in which hypotheses are constantly refined by experiment and observation,²⁵ the process involved in trans-science is frozen at an early developmental stage, consisting of a

experts agree that tests on animals, short-term tests on microorganisms, and chemical structure analyses generally provide the best, if not the only, available information about the tendency of a substance to cause chronic health impairments in humans. See WORK GROUP ON RISK ASSESSMENT, INTERAGENCY REGULATORY LIAISON GROUP (IRLG), SCIENTIFIC BASES FOR IDENTIFICATION OF POTENTIAL CARCINOGENS AND ESTIMATION OF RISKS, 44 Fed. Reg. 39,858, 39,862-71 (1979) [hereinafter IRLG WORK GROUP]; Gralla, *Protocol Preparation: Design and Objectives*, in SCIENTIFIC CONSIDERATIONS IN MONITORING AND EVALUATING TOXICOLOGICAL RESEARCH 1, 2 (E. Gralla ed. 1981) (Determination of toxicity of chemical on humans has "its genesis [in] the hands of a technician in the animal room of a toxicology laboratory, where the animal and chemical first come together."); 2 G. VETTORAZZI, HANDBOOK OF INTERNATIONAL FOOD REGULATORY TOXICOLOGY: PROFILES 1 (1981) ("The possibility of causing long-term toxic effects by the use of food additives (food colors, antimicrobials, antioxidants, etc.) has alerted toxicologists to require extensive and strict animal testing prior to utilization of these substances in food, in order to protect the health of the consumer."); WORLD HEALTH ORGANIZATION, *supra* note 22, at 74 ("Evaluation of the toxicity of chemicals in animal models of commonly occurring human diseases [is particularly valuable] . . . in evaluat[ing] experimentally the interactions between exposure to toxic chemicals and model disease conditions.").

24. It often takes five to forty years for a disease to appear after continuous, low dose exposure to a hazardous substance. During this time, the victim may be exposed to other variables which may cause a similar disease or symptoms. See J. KELSEY, W. THOMPSON & A. EVANS, *supra* note 2, at 14-16 (discussing separation of indirect causes from direct causes of disease in epidemiology studies); Hall & Silbergeld, *Reappraising Epidemiology: A Response to Mr. Dore*, 7 HARV. ENVTL. L. REV. 441 (1983); see also Rodricks & Tardiff, *supra* note 13, at 3, 4. Additionally, records of exposure may be lost in intervening years, which further complicates attempts to correlate exposure with onset of a disease.

25. Broadly speaking, competing social science theories involve adequate factual bases for judicial comparison and evaluation. Nevertheless, discontinuities between law and trans-science reemerge over such issues as insanity or addiction, where physiological or medical explanations are incomplete or frozen in hypothetical stages. For example,

Debate rages within the medical profession as to whether 'alcoholism' is a separate 'disease' in any meaningful biochemical, physiological or psychological sense, or whether it represents one peculiar manifestation in some individuals of underlying psychiatric disorders.

. . . .

It is one thing to say that if a man is deprived of alcohol his hands will begin to shake, he will suffer agonizing pains and ultimately he will have hallucinations; it is quite another to say that a man has a 'compulsion' to take a drink, but that he also retains a certain amount of 'free will' with which to resist. It is simply impossible, in the present state of our knowledge, to ascribe a useful meaning to the latter statement.

Powell v. Texas, 392 U.S. 514, 522, 526 (1968). While acknowledging these more general complexities of law and trans-science, this Note focuses on the problem in toxic tort cases of science's inability to quantify the effects of a substance on human health.

number of competing hypotheses which have never been tested or are tested only superficially and unsystematically.²⁶ The "trans-scientist" must rely largely on short-term controlled experiments conducted on laboratory animals or isolated accidents to predict the potential risks of exposure in the multi-variable outside environment. Accordingly, the realm of trans-science is characterized by an extrapolatory gap²⁷ which separates the experimentally established effects of a substance on non-humans or on humans following isolated, short-term disasters from the untested predictions of the effects on humans following exposure to low doses over a long period of time.

In the past, trans-science did not appear to pose a problem for courts, because most personal injury suits involving the effects of hazardous substances on human health were filed several decades after the substance had been released into the environment. By that time data had emerged to demonstrate with statistical certainty the magnitude of impact that the substance had on humans, and thus the probability that it caused plaintiff's injury.²⁸ The most significant trans-scientific issues, therefore, were resolved before the issue ever entered the court room. In contrast, many recent toxic tort claims have been filed while the effects of the substance

26. The degree to which an issue is trans-scientific does vary, however. First, not all substances considered in toxic torts cases are equally trans-scientific, and some are not trans-scientific in any way. The molecular structure of a chemical or the existing literature documenting a chemical's impact on health determine, to some extent, the level of certainty regarding that substance's effect on humans. Second, whether an issue is more or less trans-scientific depends on the nature of the injury inflicted. Substances that inflict diseases which are not specific to that particular chemical but instead have a high probability of natural occurrence are more trans-scientific than substances which inflict specific diseases. Asbestos and DES injuries are unusual and specific to these particular substances, thus proof of mesothelioma or adenocarcinoma, coupled with evidence of exposure to the substance, indicates an almost undeniable link. Most other substances, however, such as Agent Orange, radiation, indoor air pollutants, and hazardous wastes, inflict injuries which are common in the everyday world and therefore difficult to trace to any specific cause. Finally, the substantial lag time before any injury becomes apparent—typically several decades—adds still another trans-scientific component. In addition to the legal problems that statutes of limitations present, often the evidence, data, and other records regarding the duration or extent of exposure necessary to establish a causal relation are lost.

27. The seriousness of the extrapolatory gap depends on the strength of the assumptions, for example, selection of the proper margin of safety for extrapolating from animal studies to humans. See Wodicka, *Use of Risk Assessment and Safety Evaluation*, in *ASSESSMENT AND MANAGEMENT OF CHEMICAL RISKS* 138-44 (J. Rodricks & R. Tardiff eds. 1984). Choice of the multipliers used in extrapolating from animals to humans can vary considerably within broadly defined bounds, and the resulting choice has a profound effect on the ultimate level of safety achieved. See, e.g., Salsburg, *Statistics and Toxicology: An Overview*, in *SCIENTIFIC CONSIDERATIONS IN MONITORING AND EVALUATING TOXICOLOGICAL RESEARCH* 123, 131 (E. Gralla ed. 1981).

28. See, e.g., *Ellis v. International Playtex, Inc.*, 745 F.2d 292 (4th Cir. 1984) (husband commenced action against tampon manufacturer for death of wife resulting from toxic shock syndrome); *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1083-84 (5th Cir. 1973) (action against asbestos manufacturer for asbestosis); *Lima v. United States*, 508 F. Supp. 897 (D. Colo. 1981) (plaintiff brought suit to recover for injuries allegedly resulting from Swine Flu inoculation); see also Black & Lilienfeld, *Epidemiologic Proof in Toxic Tort Litigation*, 52 *FORDHAM L. REV.* 732, 773-75 (1984) (tracing Swine Flu case law with relevant epidemiology studies). *But cf.* Gold Note, *supra* note 11 (questioning inference from impact on general group to harm to individual plaintiff).

are still clouded by the uncertainties of trans-science—before a statistically significant number of persons have been exposed and a conclusive epidemiological study has been done.²⁹

B. *Impact of Trans-Science on the Judicial System*

When determination of the effects of a substance on human health is in this interim, trans-scientific stage, the probability that the substance might be the cause of a disease is unclear. Satisfaction of the traditional "more probable than not" standard becomes impossible, because plaintiffs cannot prove that the substance had at least a fifty percent probability of being responsible for their injuries. Courts generally deny recovery to these plaintiffs and occasionally even refuse to hear their cases.³⁰ On the other hand, once epidemiological studies are completed and the data indicates that the substance has a statistically significant effect on exposed persons, the problems of trans-science diminish and courts grant recovery in almost every plausible instance.³¹

The deterrence achieved by suits which eventually do succeed is clouded considerably by the sequence of events which must occur before the more significant trans-scientific elements are resolved. The uncertainty surrounding the extent of harm a substance will cause humans,³² the chance that adequate records of exposure will be available,³³ the probability that an epidemiology study will be done,³⁴ and the probability that it will be successful,³⁵ together reduce the likelihood that a negligent manufacturer will be found liable. The limits of the scientific process as well as finite resources to study every potential health hazard in a statistically compre-

29. See, e.g., *In re "Agent Orange" Prods. Liab. Litig.*, 611 F. Supp. 1223 (E.D.N.Y. 1985) (Vietnam veterans not participating in class action brought suit against manufacturer of Agent Orange for injuries resulting from spraying); *In re "Agent Orange" Prods. Liab. Litig.*, 597 F. Supp. 740 (E.D.N.Y. 1984) (class of veterans brought suit against manufacturer of herbicide Agent Orange for injuries allegedly resulting from spraying of Agent Orange in Vietnam); *Johnston v. United States*, 597 F. Supp. 374 (D. Kan. 1984) (four employees of aircraft instrument plant brought suit against government for cancers allegedly resulting from exposure to radiation in luminous dials); *Allen v. United States*, 588 F. Supp. 247 (D. Utah 1984) (twenty-four plaintiffs brought suit against government to recover for cancers allegedly resulting from testing of atomic weapons).

30. See *infra* notes 49–50, 66–68 and accompanying text.

31. See *supra* note 28 and accompanying text.

32. See *supra* notes 22–24 and accompanying text.

33. See Schroeder & Shapiro, *Responses to Occupational Disease: The Role of Markets, Regulation, and Information*, 72 GEO. L.J. 1231, 1234 (1984) (difficulties in studying occupational diseases after workers have left workplace or become unavailable); Trauberman, *supra* note 13, at 200 ("If a disease expresses itself long after exposure to a chemical, evidence as to its source and exposure pathways may be lost and the memories of witnesses may fade.")

34. See *supra* note 12 and accompanying text.

35. Exposures that present only a low to moderate risk may not be identified because the number of persons required for a statistically significant sample size must be very large. For a discussion of the methods used in calculating the necessary sample size, see J. KELSEY, W. THOMPSON & A. EVANS, *supra* note 2, at 277–78.

hensive way ensure that many hazards will remain undetected and their manufacturers undeterred. Moreover, even when the effects of a substance are detected, compensation may be frustrated by the manufacturer's or insurer's bankruptcy.³⁶

The case of *Parker v. Employers Mutual Liability Insurance Company of Wisconsin*³⁷ presents an excellent example of this clouded deterrence, where the uncertainties of scientific detection impede a full assessment of liability. Plaintiff Parker worked as a material handler and production operator, assembling and disassembling nuclear weapons. During his four and one-half years of employment, plaintiff was exposed daily to moderate doses of radiation. Although radiation was determined to be highly carcinogenic to animals as early as 1950, there were no conclusive investigations regarding the effects of low dosages on humans. In 1965, plaintiff was afflicted with cancer of the lymph node and sued the allegedly negligent employer. The Supreme Court of Texas affirmed the trial court's judgment for defendant, however. In its holding the court stated that, regardless of what isolated radiation studies might demonstrate, in the absence of a quantitative probability that radiation will cause cancer in humans there was no evidence indicating causation. The judge ignored the fact that he was not ruling on the weight of existing evidence, but rather on the limits of science.³⁸

Analyzing the troubling verdicts in the many cases like *Parker*, scholars have focused on the scientific difficulty of determining recovery when several possible causes of an injury exist.³⁹ To resolve the problem they suggest a proportional liability scheme that calculates damages according to the probability that the injury was caused by the defective product.⁴⁰ Such an analysis, however, assumes that the risks can be quantified. It completely overlooks the more onerous, first-order problem confronting courts

36. See Epstein, *The Legal and Insurance Dynamics of Mass Tort Litigation*, 13 J. LEGAL STUD. 475, 495-505 (1984) (discussing problems of insurance coverage in mass tort cases); Note, *The Manville Bankruptcy: Treating Mass Tort Claims in Chapter 11 Proceedings*, 96 HARV. L. REV. 1121 (1983).

37. 440 S.W.2d 43 (Tex. 1969).

38. The court did note: "This requirement does in some instances place extraordinary burdens of proof on claimants. But once the theory of causation leaves the realm of lay knowledge for esoteric scientific theories, the scientific theory must be more than a possibility to the scientists who created it." *Id.* at 49.

39. For example, Rosenberg, *supra* note 16, observed:

Mass exposure cases present two distinct varieties of specific-causation questions. First, it is often unclear which one of several manufacturers of a given toxic agent produced the particular unit of the substance that harmed the plaintiff. Second, and far more common, is the problem of determining the origin of the victim's disease.

Id. at 856 (footnote omitted); see also Black & Lilienfeld, *supra* note 28, at 750 (discussing use of epidemiology to determine probable cause).

40. See, e.g., Rosenberg, *supra* note 16, at 859 (proportional liability in relation to the probability of causation).

which arises when science is unable to offer any numerical probability of injury upon exposure to a hazardous substance. Thus, while the problem of sorting out the potential causes of an injury is serious, this Note examines the more pervasive problem of how courts should handle substantial, yet unquantifiable, risks.⁴¹

II. LEGAL BASES FOR FAILURE OF THE TORT SYSTEM WHEN CONFRONTED WITH TRANS-SCIENTIFIC ISSUES

There are two major discontinuities between trans-science and the present tort system.⁴² First, the statistical requirements for a "more probable than not" standard of causation demand a certainty in quantifying causation which trans-science is incapable of producing. Second, the rules of evidence and procedure are incompatible with the capabilities of trans-science.

A. *Causation Standards Are Incompatible with the Capabilities of Trans-Science*

The standard for proof of causation in toxic tort cases requires that the occurrence be large enough to make it "more probable than not"⁴³ that an individual plaintiff's injury resulted from a hazard produced by defendant. This involves two types of scientific proof: 1) epidemiology studies⁴⁴ indi-

41. The fact that this Note identifies the pervasive problem in toxic torts to be the treatment of cases in which no epidemiology studies have been done and that involve risks which are largely unquantified does not lead to the conclusion that a case will be easily resolved once the risks are quantified to some extent or after one epidemiology study has been completed. See Gold Note, *supra* note 11, at n.12. Multiple trans-scientific problems will remain after the risks are quantified. However, this Note asserts that these problems pale in comparison with the difficulties encountered in cases where there is no experimental data quantifying the risk, and thus the fundamental issue in dispute, the effects of a substance on human health, cannot be determined.

42. More specific impacts on the judicial system are tailored to the amount of trans-science connected with a particular issue. Relevant considerations include: (1) indeterminate/determinate plaintiffs; (2) indeterminate/determinate defendants; (3) nature of the substance; (4) nature of the exposure; (5) environment of exposure and other influences; and (6) nature of the impact. See McGovern, *supra* note 5, at 3.

43. General standards for "more probable than not" include a showing of: "(1) exposure significant enough to trigger disease; (2) a demonstrated, biologically plausible relationship between the chemical and disease; (3) the diagnosis of such disease in the plaintiff; and (4) expert opinion that the plaintiff's disease was [sic] consistent with exposure to the chemical." Hall & Silbergeld, *supra* note 24, at 445.

44. More lenient courts settle for satisfaction of this first requirement only—epidemiology studies that demonstrate twice the normal risk of disease following exposure to a substance. This "weak causation standard" has been widely criticized, however. By requiring defendants to pay full compensation not only to their actual victims, but to *all* victims inflicted with a specific disease which has a high probability of being caused by defendant, the weak version of the preponderance rule imposes excessive liability. This occurs because applying the rule for causation exceeding fifty percent disregards the responsibility of disease victims and other social factors for losses and costs attributable to background risks. In addition, the super-deterrent effect operates indiscriminately, without regard to the culpability of defendants. Rosenberg, *supra* note 16, at 881.

cating that the risk that a hazard will cause a specific injury is at least twice the normal, background level of risk for that injury,⁴⁵ and 2) medical proof which links defendant's hazard with each plaintiff's injuries.⁴⁶ Satisfaction of these requirements is generally sufficient to shift the burden to defendant, even if plaintiff's claim did not preclude all other causes.⁴⁷

In cases involving trans-science, resolution of the first element is often decisive.⁴⁸ While experimentation on animals and other organisms may indicate a plausible relationship between exposure to a substance and resulting injury, the courts' further quantitative requirement that the occurrence of the disease in those exposed to a substance be twice the background incidence creates an insurmountable obstacle in trans-scientific cases. This mandate essentially requires direct experimentation on humans, with a sample size large enough to yield statistically significant results. Consequently, when courts impose "more probable than not" or "but for" causation standards on trans-scientific issues failure is inevitable, because strong probabalistic evidence for causality is being demanded from scientists who are unable to conduct the necessary experiments.

45. The "more probable than not" standard in effect requires proof that the existence of the contested act is more probable than its nonexistence. Thus, if the normal occurrence of the injury is (y), defendant must create a condition where at least (y) additional injuries occur. The total number of injuries is then the normal occurrence (y) plus defendant's added risk (y) = 2(y) total injuries.

The rule has been accepted largely without question, perhaps because of its mathematical reasonableness. See M. FINKLESTEIN, *QUANTITATIVE METHODS IN LAW* 66 (1978). In fact, most analyses of the rule consider its ability to minimize errors: For example, if the decision probability for causation is lowered to 45% in favor of the plaintiff (e.g., plaintiff must prove 45% probability that defendant caused injury), this will increase the risk of error of unnecessarily punishing defendant by 5%. The same reasoning applies, to the benefit of defendant, if the decision probability for causation is raised to 55%. See *id.* at 66-67.

For a causation probability of less than 50%, however, the rule has the ultimate effect of completely foreclosing any imposition of liability and thus denies victims any recovery. This makes an unwanted statement that certain risks (up to two times the risk posed by natural, background conditions—which is quite considerable) are acceptable, and that losses associated with these risks should be borne entirely by victims.

46. An even stronger version of this causation standard was employed in *Johnston v. United States*, 597 F. Supp. 374 (D. Kan. 1984), where the court required proof of causation to a medical certainty. See *infra* text accompanying notes 49-50.

47. See, e.g., *American Life Ins. v. Moore*, 216 Ark. 44, 223 S.W.2d 1019 (1949) (jury award of death benefits under employee group accident policy affirmed even though medical experts admitted fatal pulmonary embolism might not have been caused by previous work-related injury); *Smith v. Humboldt Dye Works, Inc.*, 34 A.D.2d 1041, 312 N.Y.S.2d 284 (1970) (affirming Workmen's Compensation Board's award of benefits to employee engaged in dying wool yarns, even though medical experts could not definitively link employee's bladder cancer to exposure to aniline dyes).

48. The determination of specific injury causation also creates trans-scientific problems, however. For example, in tobacco litigation, determining whether cigarettes cause the emphysema in a particular plaintiff may involve medical speculation not common in other diagnoses. See, e.g., Snider, *Perspective on Emphysema*, in 4 *CLINICS IN CHEST MEDICINE: SYMPOSIUM ON EMPHYSEMA* 329, 331 (G. Snider ed. 1983) ("The problems of precise diagnosis and of accurate clinical/pathologic correlations are longstanding."). Although trans-scientific controversy may preclude recovery, the ambiguity occurs at the individual level, according to the unique strengths and weaknesses of each plaintiff's case and is thus not as momentous in scope as the trans-scientific problems posed by general causation.

The case of *Johnston v. United States* illustrates this anomalous result.⁴⁹ In *Johnston* plaintiffs alleged that their cancers were a result of daily occupational exposure to minute amounts of ionizing radiation. In denying plaintiffs recovery, the court refused to interpret the Kansas causation standard requiring proof to meet a "reasonable degree of medical certainty" as only meaning that the bulk of scientifically available data support plaintiffs. Instead, the court held that the specification necessitated "medical certainty" that plaintiffs' exposure to radiation was the cause of their resulting cancer—an imperative well beyond the capability of contemporary science. The court's words are revealing: "We can see that in matters of determining the cancer risk from low occupational doses of radiation, scientists do not deal with what exists in fact and can be measured or experimentally proven. . . . Cause in tort law needs to be founded on more than a theory or hypothesis."⁵⁰

Several judges have recognized that the traditional causation requirements are incompatible with trans-science and have responded by applying a weaker, qualitative standard.⁵¹ Because most courts have adhered to some form of "more probable than not," however, an inconsistency between courts has ensued, further eroding any predictable basis for liability.

B. *Traditional Judicial Constraints Are Incompatible with Trans-Science*

A second problem emerges when courts are forced to evaluate and interpret trans-scientific issues under existing evidentiary and procedural rules.⁵²

49. 597 F. Supp. 374 (D. Kan. 1984).

50. *Id.* at 425. Although a slightly weaker burden of proof was required to establish causation in *In re "Agent Orange" Prods. Liab. Litig.*, 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985), the result was the same. Plaintiffs were asked to produce epidemiological studies which could not be obtained, due primarily to inadequate records of exposure, in order to quantify the probability that plaintiffs' injuries were caused by the herbicide: "No acceptable study to date of Vietnam veterans and their families concludes that there is a causal connection . . ." (emphasis added).

51. See, e.g., *Allen v. United States*, 588 F. Supp. 247 (D. Utah). The court stated:

Judges and lawyers must approach with great care, the idea that court decisions can be justified solely on the findings of science, lest the quest for justice be lost along the way [quoting Markey, *Needed: A Judicial Welcome for Technology*, 79 F.R.D. 209, 211 (1979)].

In the pragmatic world of "fact" the court passes judgment on the probable. Dispute resolution demands rational decision, not perfect knowledge.

Id. at 260.

52. Constitutional requirements also appear to present obstacles to the adjudication of toxic tort cases. In the recent case of *Kenney v. Scientific, Inc.*, 212 N.J. Super. 6, 512 A.2d 1142 (1986), the court was forced to balance the Seventh Amendment right to a jury trial against the overwhelming complexity of the case which threatened the litigants' Fifth Amendment right to a fair trial. See, e.g., *In re Japanese Elec. Prods. Antitrust Litig.*, 631 F.2d 1069 (3d Cir. 1980). The court concluded that since the action for injuries caused by a toxic waste landfill involved 106 resident plaintiffs and 625

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1. *Evidentiary Standards of Admissibility*

In the courts the adversarial process seeks to determine the truth from various sets of facts collected by adverse parties. The Federal Rules of Evidence were developed to distinguish necessary and relevant facts from those that are unnecessary. Unfamiliar with the terminology and principles of science,⁵³ judges are nevertheless forced to make subtle distinctions between fact and nonfact, and between theories that are generally accepted within the scientific community and those that are controversial.⁵⁴ In cases involving trans-science, precisely these questions cannot be answered by the scientific community itself.⁵⁵ Without definitive data or experiments, there is no generally accepted or reasonable scientific basis for substantiating the finding of a causal connection,⁵⁶ and the use of indirect

various defendants and included cross claims, third party actions, multiple issues, and complicated scientific concepts, defendants' motion to strike plaintiffs' demand for a jury trial should be granted.

In order to demonstrate why this case will be too complicated and lengthy to be tried by a jury consonant with due process of law, it now becomes necessary to discuss in some detail the course that the trial will take. First, it will be necessary for plaintiffs to prove what toxic substances stored by the landfills caused the injuries or property damage allegedly suffered by plaintiffs. . . . Next, plaintiffs will have to prove which generator produced which toxic substance, and which hauler transported same to the landfill. Furthermore, each of 106 plaintiffs must in order to establish proximate cause, prove that his or her particular injury or property damage was caused by the substance in question.

. . . .
In the toxic waste case now before the court, since trial by jury will not be able to produce a fair and balanced result, the court feels impelled to protect the integrity of the judicial process by ordering that type of trial best designed to achieve justice, *i.e.*, a trial by a judge without a jury. Otherwise, the judge would not be presiding over a fair trial, but over a game of judicial Russian roulette.

Kenney, 212 N.J. Super. at 19, 22, 512 A.2d at 1149, 1150.

53. See, *e.g.*, T. KUHN, *STRUCTURE OF SCIENTIFIC REVOLUTIONS* 163-64 (1970) (discussing esoteric nature of science).

54. See *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923) ("[W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.").

55. Because of the unverifiable nature of trans-science, then, the holding of the case often becomes determined by the lawyers' persuasiveness in stressing the risks involved. Similarly, judges necessarily acquire considerable discretion in interpreting facts. For example, in *In re Agent Orange*, 597 F. Supp. at 749-50, Judge Weinstein remarked repeatedly on the extensive costs and courtroom time that would be involved and indicated his preference for resolving the case in the most expedient way—out of court; see also Peto, *Distorting the Epidemiology of Cancer: The Need for a More Balanced Overview*, 284 *NATURE* 297, 297 (1980) ("The vacuum of reliable scientific knowledge is such that each side can find scientists who will maintain in courts, in public hearings or in the scientific literature whatever is politically convenient . . . [S]cientists on both sides of this debate now have career interests at stake in it.").

56. In *Johnston v. United States*, 597 F. Supp. 374, 409-15 (D. Kan. 1984), for example, the court rejected the testimony of two expert witnesses because they had no reliable or significant evidence on which to premise their opinions; neither served on national committees chosen to address the question under dispute; neither had accepted the consensus reports of the committees as reliable authorities; and both used unreliable statistical methods not commonly used in that particular field of science. The court's conclusion was abrupt: "Thus, when the doses are so low that the existence of any effect at all is only hypothetical theory, such calculations are mere speculation. In the court's view, these calculations should not, nor will they, be accepted here as valid evidence on causation." *Id.*

extrapolations from animal studies may not be considered relevant to the effects on humans.⁵⁷ Thus, disputes over the admissibility of evidence center on the scientific validity of vying hypotheses rather than on the legal relation of relevant facts to facts that are irrelevant or have only minimal probative value.

Judicial opinions illustrate the courts' wildly varying views on the "factual" value of trans-scientific hypotheses. In *Lima v. United States*⁵⁸ the court held expert testimony to be inadmissible under Rules 702 and 703 of the Federal Rules of Evidence because the "smoldering Guillain-Barre Syndrome (GBS)" theory used to explain plaintiff's injury was not of the type "reasonably relied on by experts in the field."⁵⁹ Specifically, the court noted that while the theory demonstrated the causal connection between exposure to the Swine Flu immunization shot and resulting injuries consistent with that exposure, the factual basis to support the theory was simply too incomplete—a consequence of the small data base, not of the scientist's lack of credibility or methods of experimentation. Due to this inadequate factual basis, the court refused to grant recovery. In several other Swine Flu cases, however, courts have accepted the "smoldering GBS" theory and have granted relief to plaintiffs with claims similar to Lima's.⁶⁰

at 426. "A theory of hypothesis or assumption which yields a number like 97.6% or 8% is not yielding a real number." *Id.* at 425.

In contrast, the court in *Kehm v. Proctor & Gamble Mfr.*, 724 F.2d 613, 618 (8th Cir. 1983), admitted government epidemiological studies on Toxic Shock Syndrome, in spite of Proctor and Gamble's challenges that they were not "factual findings," not done by persons with first-hand knowledge in the field, and untrustworthy. The court ruled against exclusion on several grounds: the procedures were widely accepted in the field of epidemiology, the investigations were timely and objective, and the individuals preparing them were especially skilled. "[T]here is no reason not to admit the findings simply because they tend towards the conclusory rather than the factual end, unless . . . the sources of information or other circumstances indicate lack of trustworthiness." *Id.* at 618 (citing *United States v. American Tel. & Tel. Co.*, 498 F. Supp. 353, 360 (D.D.C. 1980)).

57. See Faulk, *Strategic and Scientific Considerations in Toxic Tort Defense*, 26 S. TEX. L.J. 513, 535-36 (1985) (use of animal studies "creates unique opportunities for defense counsel to challenge the admissibility of this progressive proof. If the plaintiff attempts to rely upon novel theories which have not been generally accepted by the scientific community, such evidence may be legally unreliable and, hence, inadmissible").

58. 508 F. Supp. 897 (D. Colo. 1981).

59. The court in *Beighler v. Kleppe*, 633 F.2d 531 (9th Cir. 1980), gave insight into the traditional application of these Federal Rules of Evidence:

Rules 702 and 704 allow properly qualified experts to testify in the form of an opinion about issues as to which their expertise may assist the trier of fact, even if the opinion embraces an ultimate issue of fact. Rule 703 permits the expert to base opinions or inferences on facts or data not admissible in evidence if they are of a type reasonably relied upon by experts in the field. Rule 705 permits an expert to give opinion testimony without prior disclosure of the underlying facts or data.

Id. at 533.

60. See, e.g., *Barnes v. United States*, 525 F. Supp. 1065 (M.D. Ala. 1981) (government held liable under "smoldering GBS" theory even though acute GBS did not develop until many months after inoculation); see also *Spencer v. United States*, 569 F. Supp. 325, 329 n.2 (W.D. Miss. 1983) (citing relevant cases).

Likewise, in *In re Agent Orange*,⁶¹ Judge Weinstein employed the Federal Rules of Evidence to remove much of the science which he considered either “irrelevant” or “conclusory.” While one of plaintiffs’ experts withstood a motion challenging his credibility, the court held his theories to be inadmissible under Rule 403. Although the court did note that the evidence might mislead “at least *some members* of the jury,” the court based its holding more solidly on the desire to put “this prolonged litigation” to an end.⁶² “In complex and protracted litigation, waste of the trier’s time is a particularly telling factor.”⁶³

2. Rules of Procedure

The Federal Rules of Procedure raise even more onerous difficulties in the evaluation of trans-scientific issues. It is the general rule that summary judgment, judgment notwithstanding the verdict, and judgment on the pleadings are granted only when there is no material issue of fact in dispute.⁶⁴ When confronted with disputes over interpretation of uncertainty, courts are generally reluctant to grant summary judgment, limiting its use to situations in which the facts are based on mere pro forma denials, sham, or patently false assertions in the pleadings.⁶⁵ These patterns

61. 611 F. Supp. 1223 (E.D.N.Y. 1985).

62. *Id.* at 1256.

63. *Id.* at 1256. Judge Weinstein, although properly aware of limited judicial resources, neglected to pay equal heed to the fundamental purpose of the judicial system—the preservation of justice.

64. “An issue of fact is deemed to be material if the outcome of the case might be altered by its resolution one way rather than another. A material issue of fact may be framed by an express conflict on a particular point between the parties’ respective pleadings.” 4 C. WRIGHT & A. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1368 (1969).

65. Although not a universal trend, there has been a strong tendency for judges to defer to juries on the issue of causation in toxic tort cases rather than to grant summary judgment. For example, in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984) (wrongful death action against manufacturer for pulmonary fibrosis resulting from long-term skin exposure to paraquat), the court found that

[i]n a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors *could* conclude from the expert testimony that paraquat more likely than not caused Ferebee’s injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant.

[When] the dose-response relationship . . . is one of the most sharply contested questions currently being debated in the medical community . . . surely it would be rash for a court to declare as a matter of law that, below a certain threshold level of exposure, dermal absorption of paraquat has no detrimental effect.

Id. at 1536. Similarly, in *Ellis v. International Playtex, Inc.*, 745 F.2d 292 (4th Cir. 1984), the court stressed the importance of a jury determination of causation and criticized those cases which leave it to the

judge’s subjective ability to ‘count heads’ among experts in the scientific community. Critics and courts . . . have argued that the acceptability of scientific data should be debated by experts before the jury.

The weight that a juror might ascribe to the data, of course, would turn on the credibility of and persuasiveness of the experts that each side offered to explain the data.

Id. at 304.

are not followed uniformly in the toxic tort area, however.⁶⁶ Judge Weinstein's ruling that animal studies and over one hundred privately conducted epidemiological studies were inadmissible⁶⁷ heavily influenced the court's determination that there were no facts in dispute in granting defendant's motion for summary judgment, because most of plaintiffs' remaining evidence relied, at least in part, on extrapolations from these excluded studies.⁶⁸

In sum, under our present system judges are called on to make scientifically delicate determinations of what is resolvable, certain, or factual in order to quantify causation under legal rules designed for more determinable situations. If lines must be drawn, they will be drawn by judges who often ignore the inherently limited capabilities of scientific research, leading inevitably to inconsistent and haphazard judgments. Such inconsistency, in turn, precludes adequate financial planning for liability by manufacturers when initially marketing the product and ultimately impairs the ability of the courts to deter wrongful conduct. Instead of providing a predictable basis for imposing liability, manufacturers will conclude that liability is based on each judge's personal perception of "fact" and "relevancy."

III. PROPOSAL FOR REFORM

In order to provide proper incentives for deterring wrongful behavior and to ensure equitable compensation to injured victims in toxic tort cases, a standard for liability must be devised which can be applied consistently

66. See, e.g., *Stiles v. Union Carbide Corp.*, 520 F. Supp. 865 (S.D. Tex. 1981) (summary judgment granted to defendants in wrongful death resulting from exposure to toxic chemicals because evidence of defendant's concealment of hazardous nature of chemicals was insufficient to toll statute of limitations); *Synalloy Corp. v. Newton*, 254 Ga. 174, 326 S.E.2d 470 (1985) (employees brought suit against employer for negligent exposure to carcinogenic betanaphthylamine; court granted summary judgment to defendant employer because disabilities had not yet manifested and Georgia statute of limitations barred employee claims one year following exposure).

67. "A number of sound [governmentally conducted] epidemiological studies have been conducted on the health effects of exposure to Agent Orange. These are the only useful studies having any bearing on causation. All the other data supplied by the parties rests on surmise and inapposite extrapolations from animal studies and industrial accidents." *In re Agent Orange*, 611 F. Supp. at 1231. Weinstein did not support his decision to exclude all epidemiology studies not conducted by the government except by asserting that *some* of the studies relied on inapposite data or were flawed. *Id.* at 1241. The exclusion of all animal studies was based on the fact that the concentrations used in the animal studies were higher than those in the environment and because the animal studies "involve different biological species." *Id.* Judge Weinstein ignored the fact that extrapolation from animal studies is a widely utilized scientific method. See *supra* note 23.

68. 611 F. Supp. at 1259-60. Judge Weinstein's unsupported and seemingly harsh ruling contrasts with traditional features of conclusory allegations: unsupported evidence (no connection between fact and allegations); incomplete evidence; contradiction of known facts that both parties agree on; and internally inconsistent claims. See, e.g., *Cunningham v. Rendezvous, Inc.*, 699 F.2d 676, 678 (4th Cir. 1983) (expert hypotheses regarding sinking of vessel excluded because flatly inconsistent with uncontroverted facts); *Merit Motors, Inc. v. Chrysler Corp.*, 569 F.2d 666, 673 (D.C. Cir. 1977) (expert opinion excluded because economic theory wholly unsupported by facts of case).

and clearly. The standard must adjust to the inability of trans-science to quantify the effects of a substance. It must also resolve or circumvent the evidentiary and procedural problems resulting from the inherently hypothetical, rather than factual, nature of trans-science. The reform proposed by this Note would shift the burden of proof to the defendant following 1) proof of qualitative causation and 2) proof that the product was “abnormally dangerous.”⁶⁹ Together, these requirements should ensure that plaintiffs will have their cases heard, while the manufacturers will have a consistent basis for predicting future liability.⁷⁰

A. *Qualitative Causation*

Under the present “more probable than not” causation requirements, plaintiffs in toxic tort cases are unable to sustain their burden of proof because the resulting injuries have not been statistically detected by epidemiologists. The procedural burden of proof, however, should be refocused on the underlying realities of the typical toxic tort case. Plaintiffs injured by hazardous products must have the power to be heard, despite the fact that the statistical impact of the hazard has not yet been determined. The revised causation standard should be based, then, on more qualitative elements of causation,⁷¹ such as proof that the plaintiff was exposed to sub-

69. Although Gold Note, *supra* note 11, does not address the toxic tort cases in which statistical evidence is not yet available, his proposal resembles this Note’s advice for reform. First, Gold indicates that fault and negligence may become important factors in the determination of liability, even though he chooses not to include them explicitly in his standard. Second, Gold suggests a burden of proof/burden of persuasion standard which abandons the present single, numerical “more probable than not” approach and incorporates more qualitative judgments, such as a “substantial factor” test. Thus, Gold too selects a qualitative causation standard over a quantitative one. Application of Gold’s “substantial factor” test to cases which are highly trans-scientific, however, may still require courts ultimately to select a winning (or “substantially” convincing) hypothesis. In contrast, the qualitative causation standard set forth in this Note seeks to avoid scientific hypothesizing by judges and juries by encouraging the production of more scientifically established criteria for determination of causation, including proof of exposure to a hazardous substance and proof of an injury consistent with such exposure.

70. Reincorporating notions of negligence while simultaneously weakening the necessary proof of causation may cause earlier imposition of liability—before the risk is tested on humans—to the disadvantage of manufacturers. But, many manufacturers may prefer a more predictable basis for risk, perhaps even at the cost of imposing liability earlier. Additionally, since manufacturers often are both in more informed positions and are imposing their products on involuntary, non-purchasing plaintiffs, there is potentially less cost in attaching greater burdens on defendant manufacturers. Finally, fairness demands that a risk of error falling on plaintiffs should be partially shifted to defendants because, at present, a substantial number of deaths are necessary before liability is imposed.

71. In fact, the *Restatement (Second) of Torts* mentions causation, but does not specifically interject proximate cause requirements into the strict products liability doctrine.

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought

stantial concentrations of the substance and was afflicted with an injury consistent with the known hazards of that substance. In fact, this qualitative causation standard, standing alone, was used to shift the burden of proof to defendants in *Allen*⁷² and has been suggested in Congress as a statutory reform.⁷³

This qualitative standard, unlike its present quantitative counterpart,⁷⁴ utilizes all available information regarding the hazardous substance, as well as extrapolatory techniques, to determine potential effects on humans. The difficulty of resolving trans-scientific problems is also eased by a requirement that plaintiffs need only prove that a substance is capable of causing an injury consistent with their injury. This burden may be satisfied by a thorough search of studies on the effects of the substance on animals⁷⁵ or on humans in occupational settings and following disasters.⁷⁶

the product from or entered into any contractual relation with the seller.

RESTATEMENT (SECOND) OF TORTS § 402A (1977).

72. 588 F. Supp. at 428. *Allen* involved the effects of atomic radiation on human health, a trans-scientific issue similar to Agent Orange in which the relevant epidemiological studies are not complete. In *Allen* the court shifted the burden of proof upon a showing that ionizing radiation was hazardous (based on animal studies and reports of human injuries resulting from occupational exposures and industrial accidents); that plaintiff was exposed to substantial concentrations of the radiation; and that plaintiff's injury was consistent with such radiation. In setting forth the rationale for this burden shifting, the court stated:

This shift in burden of proof reflects a sound application of important legal policies to the practical problems of trying a lawsuit: where a strong factual connection exists between defendant's conduct and the plaintiff's injury, but selection of "actual" cause-in-fact from among several "causes" is problematical, those difficulties of proof are shifted to the tortfeasor, the wrongdoer, in order to do substantial justice between the parties.

Id. at 411.

73. Several bills introduced in Congress in 1979 and 1980 proposed similar qualitative causation standards: 1) Claimant must have been exposed to a hazardous substance released by the defendant; 2) Exposure must be in sufficient concentration and of sufficient duration to create a "reasonable likelihood" that it caused or contributed to the claimant's injury; and 3) There must be a "reasonable likelihood" that exposure to the substance causes or contributes to the type of injury sustained by the claimant. S. 1480, 96th Cong., 2d Sess. § 4 (1980); see also H.R. 1049, 96th Cong., 1st Sess. §§ 101-106 (1979); H.R. 3797, 96th Cong., 1st Sess. §§ 3211-3215 (1979); H.R. 5291, 96th Cong., 1st Sess. §§ 211-215 (1979). In contrast to the reform set forth in this Note, however, these legislative proposals specify that negligence or some showing of fault are not necessary for compensation.

Although these bills were not passed into law, a Senate Committee did undertake a formal study of the problems unique to toxic torts and made recommendations for a compensation scheme which were similar to those set out in the Senate bill. Under this proposal, proof of causation is shifted to defendant once proof is adduced showing that claimant was exposed to a hazardous substance and suffered injury that is known to result from such exposure. S. REP. NO. 12, 97th Cong., 2d Sess. 214 (1982).

74. See *supra* notes 44-47 and accompanying text.

75. For example, human and animal responses are qualitatively similar with respect to all human carcinogens, except arsenic. See, e.g., IRLG WORK GROUP, *supra* note 23, at 39,875; Karstadt, *Protecting Public Health from Hazardous Substances: Federal Regulation of Environmental Contaminants*, 5 *Envl. L. Rep.* (Envtl. L. Inst.) 50,165, 50,168 (1975). For a discussion of methods of extrapolating from animal studies, see V. BROWN, *ACUTE TOXICITY IN THEORY AND PRACTICE* (1980); E. CALABRESE, *PRINCIPLES OF ANIMAL EXTRAPOLATION* (1983); W. ROWE, *supra* note 23, at 31-32; WORLD HEALTH ORGANIZATION, *supra* note 22, at 35-41; Salsburg, *supra* note 27, at 126-36.

76. See, e.g., J. CAIRNS, *CANCER: SCIENCE AND SOCIETY* 53-57 (1978); Reggiani, *Anatomy of a TCDD Spill: The Seveso Accident*, in 2 *HAZARD ASSESSMENT OF CHEMICALS* 295-324 (J. Saxena

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Focusing litigation on the qualitative, resolvable aspects of causation also avoids the evidentiary problems presented by trans-science. Under the present "more probable than not" standard, admissibility is dependent upon 1) whether each court wishes to view unverified hypotheses of a substance's effect on humans as accepted as reasonable within the scientific community, and 2) whether extrapolations from the effects of a substance on animals are relevant to humans. Under the proposed qualitative standard, however, evidentiary questions will involve more commonplace disputes over the facts related to exposure and to diagnosis of injuries in plaintiff that are consistent with the known hazards of the substance. Similarly, procedural rulings will be based on the weight of all evidence, unlike the present rulings which consider only the scant evidence that remains after all non-human and inconclusive or irrelevant human studies have been ruled inadmissible.

B. *Abnormally Dangerous*

Under the existing strict liability standard, relaxing plaintiffs' burden of proof on causation, however necessary from the standpoint of fairness, would subject manufacturers to inordinate liability. Manufacturers would be overdeterred and held accountable for injurious effects that were undetectable when the products were marketed.⁷⁷ Hence, before the burden of proof shifts to defendant, plaintiffs ought to be required to prove that the product was "abnormally dangerous" in light of the manufacturer's knowledge at the time of marketing. The standard suggested here employs "abnormally dangerous" as a gauge for unreasonable conduct,⁷⁸ which differs from the term's strict liability use in the *Restatement (Second) of Torts*.⁷⁹ In short, the two-tiered requirement for liability based on quali-

ed. 1983).

77. Although the *Allen* court did not explicitly balance the qualitative causation standard with any additional basis for culpability, Judge Jenkins apparently perceived the defendant's clearly negligent behavior as an important factor in the decision to impose liability:

There are serious legal problems here, but legal problems have pragmatic solutions. The statistics can establish the number of 'culpably injured' plaintiffs. If the court can then find a relationship between the defendant's conduct and the plaintiff's injuries, the defendant has to prove otherwise. Even where there remains the possibility that the injury would have occurred in the absence of defendant's conduct . . . doing justice between the parties requires that the party creating a materially increased risk of that harm bear at least the economic burden of its consequences.

Yates, *The Torts of Last Resort*, STUDENT LAW., Apr. 1985, at 28, 31-32 (quoting Jenkins, J.).

78. In fact, despite the no-fault scheme articulated under the strict liability doctrine, courts apparently consider the foreseeability of the risk in assessing liability. See Polelle, *The Foreseeability Concept and Strict Products Liability: The Odd Couple of Tort Law*, 8 RUT.-CAM. L.J. 101, 103-09 (1976). Consequently, this proposal would not change the case law but would only make the basis for judgments more explicit and predictable.

79. In determining whether an activity is abnormally dangerous under the RESTATEMENT (SECOND) OF TORTS, the following factors are to be considered:

tative causation and unreasonable conduct ensures that incentives to create necessary products for human use are properly balanced with the need to deter the manufacture of unsafe products.⁸⁰ The "abnormally dangerous" standard rests on foreseeability of harm⁸¹ and thus incorporates traditional negligence concepts.⁸² First, the jury must determine whether a hazardous substance was marketed after the manufacturer "should have known" of its hazardous nature.⁸³ If the jury confirms such knowledge, it will then

- (a) existence of a high degree of risk of some harm to the person, land or chattels of others;
- (b) likelihood that the harm that results from it will be great;
- (c) inability to eliminate the risk by the exercise of reasonable care;
- (d) extent to which the activity is not a matter of common usage;
- (e) inappropriateness of the activity to the place where it is carried on; and
- (f) extent to which its value to the community is outweighed by its dangerous attributes.

RESTATEMENT (SECOND) OF TORTS § 520 (1977).

80. One of the basic goals of strict liability is to discourage the manufacture of commodities dangerous to the public and encourage the development of higher safety standards by placing the costs of accidents on those who control the production and distribution of products. *See Escola v. Coca-Cola Bottling Co.*, 24 Cal. 2d 453, 150 P.2d 436 (1944) (soft drink bottler and distributor liable for explosion of bottle of Coca-Cola, despite neither clear showing of cause of explosion nor proof of plaintiff's due care). As Justice Traynor noted:

It is to the public interest to discourage the marketing of products having defects that are a menace to the public. If such products nevertheless find their way into the market it is to the public interest to place the responsibility for whatever injury they may cause upon the manufacturer, who, even if he is not negligent in the manufacture of the product, is responsible for its reaching the market.

Id. at 462, 150 P.2d at 441 (Traynor, J., concurring).

81. In contrast with this proposal, other courts impose complete liability, without regard to prior knowledge or foreseeability. For example, in *Beshada v. Johns-Manville Prods. Corp.*, 90 N.J. 191, 447 A.2d 532 (1982) the court found that "negligence is conduct-oriented, asking whether defendant's actions were reasonable; strict liability is product-oriented, asking whether the product was reasonably safe for its foreseeable purposes." *Id.* at 200, 447 A.2d at 544. In addition, the court noted that "a major concern of strict liability—ignored by defendants—is the conclusion that if a product was in fact defective, the distributor of the product should compensate its victims for the misfortune that it inflicted on them." *Id.* at 204, 447 A.2d at 546; *see also Little v. PPG Indus.*, 19 Wash. App. 812, 821–22, 579 P.2d 940, 946 (1978) (in wrongful death action resulting from use and exposure to manufacturer's chemical product, court dismissed negligence action noting that "strict liability (as distinct from negligence) for a manufacturer's failure to provide adequate warnings does not depend on the manufacturer's knowledge of the danger"), *aff'd as modified*, 92 Wash. 2d 118, 594 P.2d 911 (1979).

82. Traditional negligence differs from the abnormally dangerous standard proposed in this Note only insofar as "reasonableness" is concerned. Whereas the negligence standard holds defendant to the level of a "reasonable man," the "abnormally dangerous" standard holds manufacturers to the level of an expert—responsible for all information available when products are marketed. Whether a particular manufacturer is aware of the hazards is immaterial since expert knowledge is imputed to every manufacturer.

83. The standard is based on all relevant information; that is, the supplier is presumed to know all the dangers that exist in a product at the time it is marketed. Since much of this imputed knowledge will be present in the published toxicology and medical literature, *see supra* text accompanying notes 75–76, discovery generally will be unnecessary in the early stages of trial. In addition, the manufacturer will have a duty to test at least to the level required by the relevant statute. Presently, pre-testing requirements under a variety of statutes are not met—a consequence of weak or nonexistent enforcement. *See supra* note 14. With liability based on the duty of manufacturers both to consult the literature and also to perform all appropriate regulatory tests, as this Note urges, private parties will not only enforce their own rights in bringing toxic tort suits, but will aid in the policing and enforcement of a manufacturer's statutory responsibilities.

employ more traditional strict liability concepts to determine liability, weighing the costs of the uncertain hazardous risk which the product presented at the time of marketing⁸⁴ against its apparent benefits to society. The jury will proscribe a product as "abnormally dangerous" if it makes both findings: 1) the manufacturer "should have known" of the hazardous nature of a product; and 2) the costs of the hazard outweighed its benefits to society at the time of marketing.⁸⁵

Although the cost/benefit approach to "abnormally dangerous" requires case by case inquiry, in most cases juries are likely to weigh the quantity and quality of animal studies and disaster or occupational reports existing at the time of marketing against the economic and social utility of the product at that time. These determinations do not involve complex numerical weighting, but require only that the jury consider qualitatively which sorts of risks society wishes to assimilate and which it chooses to deter.⁸⁶

Because it relies on deterring knowable but unreasonable risk, this "abnormally dangerous" standard also comports with traditional cost spreading notions. Manufacturers will be held liable for, and thus have financial incentives to internalize, the costs of the unreasonable and preventable risks which their products create. If, on the other hand, the jury determines that the benefits of the product are considerable, the product may still be marketed with adequate warnings to alert the user.⁸⁷ When the

84. Factors to be considered include the normal expectations of the consumer as to the manner in which the product will be used, complexity of the procedures consumers must follow to use it, magnitude of the danger to which the user will be exposed, and likelihood of harm to the user. *See Sales, The Duty To Warn and Instruct for Safe Use in Strict Tort Liability*, 13 ST. MARY'S L.J. 521, 527 (1982).

85. The court in *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984) (action against manufacturer of tetracycline drug for side effect of tooth discoloration) undertook a similar analysis of "abnormally dangerous," camouflaged as a discussion of strict liability:

[O]nce the defendant's knowledge of the defect is imputed, strict liability analysis becomes almost identical to negligence analysis in its focus on reasonableness of the defendant's conduct. [The standard is] would a person of reasonable intelligence or of the superior expertise of the defendant charged with such knowledge conclude that defendant should have alerted the consuming public?

Id. at 451-52, 479 A.2d at 385-86.

86. The balancing of the costs and benefits of a risky product is a traditional jury function. There is no more scientific speculation inherent in this decision than in other jury decisions that involve lack of due care in design cases. Page, *Generic Product Risks: The Case Against Comment K and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 873 (1983); *but cf.* *Kenney v. Scientific, Inc.*, 212 N.J. Super. 6, 512 A.2d 1142 (1986) (court denied jury trial due to complexity of technical scientific concepts inherent in "more probable than not" causation determination).

87. Warnings are adequate if they provide users with complete information regarding risks, *see, e.g., Henderson, Coping with the Time Dimension in Products Liability*, 69 CALIF. L. REV. 919, 946-48 (1981); *but cf. Cooper, Freedom of Choice in the Real World*, 34 FOOD DRUG COSM. L.J. 612, 618-23 (1979), but federally mandated warnings, standing alone, may not be adequate under the common law, *see, e.g., Ferebee*, 736 F.2d at 1539-43 (EPA approved warnings on herbicide did not make warnings adequate as matter of law); *Brochu v. Ortho Pharmaceutical Corp.*, 624 F.2d 652, 658 (1st Cir. 1981) (manufacturer held liable for failing to include warning that oral contraceptives

potentially dangerous nature of the product is within reasonable contemplation and knowledge of the user, however, the product may not need a warning.⁸⁸

This "abnormally dangerous" standard will also avoid the evidentiary problems posed by trans-science. The current focus by courts on the viability of competing trans-scientific hypotheses, which attempt to quantify the untested effects of a substance on humans, will shift to negligence questions of reasonable conduct. Moreover, such conduct will be adjudicated in light of the published literature and the manufacturer's satisfactory completion of necessary tests—issues which are determinable. As a result, deterrence will be enhanced in a predictable manner by shifting the burden of proof to manufacturers who negligently market hazardous products, despite the trans-scientific inability to quantify such hazards with certainty.

In sum, basing liability on a qualitative showing of causality and on proof that the manufacturer acted negligently in marketing an "abnormally dangerous" product will provide a firm basis for deterrence while conforming to traditional tort requirements.⁸⁹ It should also be noted that although the proposed liability standard is intended to address trans-scientific problems, its use need not be so limited.⁹⁰ Revising the criteria upon which a shift in the burden of proof is based insures that negligent manufacturers must prove that a trans-scientific substance is safe. Thus, when the issue is no longer trans-scientific and the relevant epidemiological studies have been done, or when the manufacturer is able to prove that the product is not hazardous, that the product did not cause plaintiff's injury, or that the plaintiff was contributorily negligent, then the manufacturer may rebut the presumption and shift the burden of proof back to plaintiff. Although this process may involve an additional burden shift in

taken in high dosages substantially increased risk of cerebral thrombosis, despite fact that existing warnings were drafted by FDA).

88. See *Osterdorf v. Brewer*, 51 Ill. App. 3d 1009, 1013-14, 367 N.E.2d 214, 217 (1977) (plaintiff could not recover damages resulting from injury when gasoline cap flew off fuel tank of tractor, because plaintiff admitted he knew of necessity of tightly securing gasoline cap after refueling).

89. While this Note's proposal does set forth novel proof requirements for "abnormally dangerous" products and qualitative causation, these requirements comport with the basic goals of the strict liability doctrine—cost-spreading and incentives to maximize safety. See, e.g., Ginsberg & Weiss, *Common Law Liability for Toxic Torts: A Phantom Remedy*, 9 HOEFSTRA L. REV. 859, 905-06 (1981).

90. This proposed standard does not address one set of cases—those in which plaintiffs were injured by a hazardous substance but the manufacturer cannot be held negligent because detection of the hazardous nature of the product was beyond the capabilities of contemporary science. Though the victims deserve compensation, imposing liability on the manufacturer would obviously not further deterrence. *But cf. supra* note 81. When a strict liability theory would not provide compensation, the legislature may wish to intervene and provide a compensation fund for the victims of certain unforeseen risks which society chooses to incur in pursuit of technical innovations and scientific progress. For a brief discussion of such compensation funds, see Trauberman, *Compensating Victims of Toxic Substances: An Analysis of Existing Federal Statutes*, 7 HARV. ENVTL. L. REV. 1, 3-4 (1981).

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cases where the most significant trans-scientific elements have been resolved, it does not affect the ultimate basis for imposing liability.

IV. CONCLUSION

Trans-science in toxic torts presents an obstacle in traditional tort litigation which not only produces confusing and inconsistent judgments, but also makes it difficult or impossible to preserve the goal of deterrence. In order to accommodate trans-science, the judicial framework must change. A proposal for reform is suggested in which trans-scientific obstacles can be circumvented by referring to more predictable notions of qualitative causation and unreasonable conduct. By adopting such a proposal, the courts may be able to reincorporate the principle of deterrence into the adjudication of toxic torts.

