Use of Comparative Risk Methods in Regulatory and Common Law

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I. Introduction

Several persistent problems afflict risk decisionmaking. In the regulatory context, agencies confront the problems of how to prioritize risks for best use of their limited resources and how to determine "how safe is safe enough," or a risk limit, when action is to be taken on a particular risk.

In the trial courts hearing toxic tort actions, the jury must often determine whether an activity is "unreasonably dangerous" or a product is "defective" because of its risk attributes.

To resolve these problems, many have proposed the use of risk comparisons. Now that we can quantify risks, why not compare them when regulatory priorities and risk limit issues are raised in the agencies and courts, in order to facilitate decisionmaking?

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This Article discusses these proposals, reviews cases in which risk comparisons have been offered or relied on to deal with the problems and evaluates this experience from a legal and policy analysis perspective. Several issues are identified which obstruct wider acceptance of risk comparisons, and recommendations are presented for resolving these issues.

II. PROBLEMS IN RISK DECISIONMAKING

Decisions for controlling technological risk are made in two legal domains: regulatory law and common law.

In regulatory law, decisions are made to prevent future risks and reduce existing risks in accordance with statutory authorizations. Thus, legislatures select which categories of risk merit regulatory action and enact statutes to authorize agency regulatory efforts. Agencies, in turn, select specific risks within the authorized category for regulatory action and then set standards or make licensing decisions to control these risks consistent with the statutory mandate. Courts then review those agency decisions which are appealed (the judicial review function) and either affirm or invalidate the agency decisions.[1]

In the common law, decisions are made to abate existing risks and compensate for harms. State and federal courts hear common law actions brought by persons who claim personal injury or property damage and seek compensation, injunctive relief and other remedies as a result of the risky activities or products of another. These actions are premised on tort theories of negligence, strict liability and products liability, and on various contract and breach of warranty theories.[2]

Several persistent problems plague risk decisionmaking in both domains. In regulatory law, a critical issue is how to determine which risks deserve priority for action and the allocation of limited regulatory resources. This issue may arise at several levels: (1) when the legislature is faced with several categories of risk as

1. *See generally* J. FIKSEL, M. BARAM, L. COX & J.R. MIYARES, PRINCIPLES FOR USE OF DE MINIMIS CONCEPTS IN RISK REGULATION 18-32 (1984) (report to the National Science Foundation describing the role of statutory language in the regulatory process) [hereinafter FIKSEL & BARAM] (copy available by writing Joseph Fiksel at Teknowledge, 1850 Embarcadero Road, P.O. Box 10119, Palo Alto, Cal. 94303). *See* Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987), *infra* note 43, for a particularly relevant example.

2. *See generally* G. NOTHSTEIN, TOXIC TORTS: LITIGATION OF HAZARDOUS SUBSTANCE CASES §§ 11 & 12 (1984) (discussing theories of liability and remedies).

candidates for statutory enactment of a regulatory program and must choose which categories merit legislative action and funding; (2) after the legislature has chosen a particular risk category for enactment, when it seeks to provide language in the statute to direct the agency on how to choose which of the numerous risks within the selected category deserve priority of agency attention and resource commitment; and subsequently, (3) when the agency seeks to use its limited resources in the most effective manner and thereby seeks to prioritize the many specific risks which fall within its statutory mandate, in order to choose which risks it will act on. Since legislative directions to the agency are often incomplete or ambiguous as to prioritization, the agency usually has considerable discretion in structuring its prioritization of risks.[3]

A second critical issue in regulatory law is how to determine the "risk limit," which is the maximum extent to which a selected risk should be reduced. Most statutes provide agencies with directions as to the process and criteria to be used in regulating risks, but few provide complete guidance on how stringently to control the risks. As a result, in most cases the "risk limit" issue is left to agency judgment and judicial review, and the outcomes embodied in standards and licensing decisions are variable in their stringency. Thus, an agency may set different risk limits for each of several toxic chemicals under the same statutory mandate; and the same toxic chemical, subject to regulation by several agencies (e.g., Environmental Protection Agency, Occupational Safety and Health Administration, Consumer Product Safety Commission) acting independently under different statutory mandates, may be controlled to differing risk limits and lead to differential protection of exposed persons (e.g., community residents, workers, and consumers).[4] This lack of uniformity in setting risk limits creates an aura of arbitrariness about agency decisionmaking and probably promotes controversy and appeals for judicial review.[5]

3. For discussions of these and related matters, see generally *Comparative Risk Assessment: Hearings Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 96th Cong., 2d Sess. (1980). *See infra* notes 25-34 and accompanying text.

4. Hattis, Goble & Ashford, *Airborne Lead: A Clearcut Case of Differential Protection*, 24 ENVIRONMENT 14 (Jan./Feb. 1982) (discussing the disparity of health protection afforded by EPA and OSHA regulation of airborne lead).

5. *See* FIKSEL & BARAM, *supra* note 1, at 101-33 for general discussion as well as detailed analyses of agency decisionmaking on risk limits under six statutes. *See generally* W.D. ROWE, AN ANATOMY OF RISK 3 (1977), for a discussion of "three major questions:" (1) what

Finally, in the common law, there is a counterpart "risk limit" issue: how to determine if an activity has been unreasonably risky, or if a product is "defective."[6] In other words, what level of foreseeable risk must be shown to prove defendant's negligent or other tortious behavior or breach of product warranty? In each state common law system, these are generally viewed as factual issues for jury determination, or for the presiding judge in non-jury cases. But theories of liability, precedents and rules of evidence which govern the risk testimony of expert witnesses differ in each state. Further, jury and judicial attitudes and understanding of risk matters are variable. As a result, court decisions reflect a diversity of views about risk limits and, in the view of many risk experts and other observers, these decisions also reflect irrational jury expectations that technological activities and products be virtually risk-free.[7]

These problems of risk decisionmaking can therefore be characterized as follows:

(1) prioritization of risks for regulatory action, a function of legislatures and agencies;
(2) setting risk reduction limits, a function of legislatures, agencies and courts.

Various methods have been proposed and used to address these problems, chiefly the "rational" methods of engineering economics such as cost-benefit and risk-benefit analysis. Proponents have included Presidents Carter and Reagan and their Offices of Management and Budget, various agencies (e.g., Nuclear Regulatory Commission), industry and economists generally.[8] But use of these techniques requires the arbitrary monetization and discounting of unquantifiable health and environmental considerations and other methodological problems, yields a range of

is risk, (2) how may different types of risks be compared for making risk decisions and (3) how can acceptable levels of risk for specific activities be determined.

6. *See generally* W. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER AND KEETON ON THE LAW OF TORTS §§ 78, 99 (5th ed. 1984) (abnormally dangerous things and activities, dangerously defective or unsafe products) [hereinafter PROSSER AND KEETON ON TORTS]; G. NOTHSTEIN, *supra* note 2, § 11 (theories of liability).

7. Determinants of jury behavior is an extensively studied subject. *See generally Research on Juries*, 11 THE JUSTICE SYSTEM JOURNAL 1 (1986) and Hinchcliff, *Portrait of a Juror: A Selected Bibliography*, 69 MARQ. L. REV. 495 (1985/1986).

8. *See, e.g.*, Baram, *Cost-Benefit Analysis: An Inadequate Basis for Health, Safety and Environmental Regulatory Decisionmaking*, 8 ECOLOGY L.Q. 473, 479-80 (1980). *See also* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, TECHNOLOGIES FOR ASSESSING CANCER RISKS SUMMARY at 19-20 (1981) (noting support for increased use of cost-benefit analysis).

"justifiable" results without specifying any precise ordering of risks or precise limit for any risk, and conflicts with various statutory mandates and public values.[9] As a result, these methods have been widely rejected by the public and in several instances by the courts.[10]

Others have looked beyond these "rational" or quantitative methods to more qualitative concepts which may appeal to common sense, be more amenable to public understanding and prove more consistent with the statutory mandates for regulation: the concepts of de minimis risk and comparative risk. Both concepts are now being considered, and in some instances are being used, in regulatory and common law proceedings. Since uses of the de minimis risk concept have recently been evaluated elsewhere,[11] this paper focuses on the comparative risk concept and its potential for solving the problems of prioritizing risks and setting risk limits.

III. Proposals to Use Comparative Risk

As its name implies, the comparative risk concept provides that the importance of a particular risk can be better understood and communicated if it is compared to other risks which are already known or familiar.

Over the last decade, academics and risk analysts have put forth the concept of comparing risks, along with tabulations of numerous risks to facilitate the comparisons, for several purposes: to advocate certain technologies over others,[12] to illuminate the arbitrariness of government efforts at risk reduction,[13] to improve public perception and understanding of risk,[14] to foster public ac-

9. *See, e.g.*, Baram, supra *note* 8, at 526-27.

10. *Id. See also* American Textile Mfrs. Assoc. v. Donovan, 452 U.S. 490, 506-22 (1980) (rejecting argument that section 6(b)(5) of the Occupational Health and Safety Act requires OSHA to perform cost-benefit analysis).

11. *See* Fiksel & Baram, *supra* note 1. *See also* Mumpower, *An Analysis of the De Minimis Strategy for Risk Management*, 6 Risk Analysis 437 (1986).

12. *See* E. Crouch & R. Wilson, Risk/Benefit Analysis 103-63 (1982) (nine examples of government or private studies using risk analysis to compare, among other things, the efficacy of various auto safety devices, the risks and benefits of coronary artery surgery versus more conservative treatment and the risk of conventional copper mining versus mining assisted by nuclear explosions); Inhaber, *Risk with Energy from Conventional and Nonconventional Sources*, 203 Science 718 (1979) (comparing risks to human health from five conventional and six nonconventional energy-producing methods).

13. *See* Kletz, *What Risks Should We Run?*, 74 New Scientist 320 (1977).

14. *See* Slovic, *Informing and Educating the Public and Risk*, 6 Risk Analysis 403 (1986).

ceptance of "expert" approaches to risk,[15] to develop a professional consensus as to a systematic approach for agency risk analysis[16] and to stimulate public concern and self-help measures.[17]

To support their arguments, these proponents have compared diverse risks expressed in various formats, including: voluntary/involuntary risk of death per person per year, accident frequency rates, estimated loss of life expectancy, increased chance of death in any year, public perceptions, acute oral toxicities of various substances and various consequence scales. The tabulated risks cover a broad spectrum from smoking to parachuting to coal mining to death from being struck by meteorites. The risk estimates are usually provided without reference to their sources or discussion of the variable quality of the studies and diversity of assumptions which produced the numbers.

In recent years, the concept has been put to use in several adversarial contexts (e.g., in the agencies and courts), either as part of the advocacy strategy of the proponents of a risky technology seeking less stringent regulatory decisions, or as support offered by regulatory officials to defend an intended decision from critics. For example, in agency standard-setting proceedings on particular risks, industry advocates have put forth risk comparisons to argue that the levels of regulation for these risks should not be more stringent than the levels tolerated or accepted for other risks. Risk analysts and other experts are frequently hired to testify on risk comparisons in these proceedings.

Inevitably, these advocacy uses have generated criticisms about the objectivity and validity of the comparisons offered, the qualifications of the experts and the relevance of the concept. Some critics range more broadly to deal with larger issues of professional responsibility, the elitism and disdain for public concerns inherent in risk analysis and its advocacy uses, and the need to reinforce informed public consent and social choice in a technocratic society. Thus, Otway damns the whole enterprise:

15. *See* Keeney & von Winterfeldt, *Improving Risk Communication*, 6 RISK ANALYSIS 417 (1986).

16. Lawless, Jones & Jones, *Methods for Comparing the Risks of Technologies*, in RISK EVALUATION AND MANAGEMENT 157 (V. Covello, J. Menkes & J. Mumpower eds. 1986).

17. For example, recent EPA efforts to publicize radon hazards. *See Radon: Threat Is Real, but Scientists Argue Over Its Severity*, N.Y. Times, Sept. 2, 1986, at C1, col. 1.

> "*Acceptable risk*" was a numbers game in which we tried to define quantitative criteria by which the social acceptability of risks and, implicitly, of technologies could be judged. These studies were inspired by the fact that, contrary to the expectations of technical experts, the public were not convinced by probabilistic risk calculations that their concerns about new technologies were groundless. The methods used ranged from primitive comparisons of estimated risks with dissimilar risks accepted in everyday life, to those involving sophisticated mathematics, eccentric philosophies, or both. Public fears were often ridiculed as being "irrational" . . . .
>
> Later research showed there are other, objective characteristics of risk besides death and injury which matter to people (such as voluntariness, control, delay, catastrophic potential), and that it is perfectly normal to care about them. The view of decision-making implicit in acceptable risk studies could be called technocratic, elitist or maybe just "perfect-world" analysis, but it did nothing to further democratic process because the judgment of acceptability was seen as a matter for risk experts—that we could tell people what was best for them.[18]

Others have sought to redeem comparative risk by evaluating its potential for improving risk analysis, communication with the public and social choice. For example, Slovic argues that:

> Doing an adequate job of communicating means finding comprehensible ways of presenting complex technical material that is clouded by uncertainty, and is inherently difficult to understand . . . .[19]
>
> . . . .
>
> The right of citizens, patients, and workers to be informed about the hazards to which they are exposed from their daily activities, their medical treatments, and their jobs, provides the motivation behind much of the efforts to communicate information about risks. . . . [T]here is a need for a deeper understanding of the concept of consent as well as for a theory of informed consent that sets out criteria for evaluating the adequacy of information presentations. . . .[20]
>
> . . . .
>
> . . . Perhaps we can learn, by studying people's understanding of commonly used measures, such as distance, time, and speed, whether and how their understanding of quantitative risk can be improved.[21]

18. H. Otway, Experts, Risk Communication and Democracy 3 (Nov. 9-12, 1986) (keynote address, annual meeting of the Society for Risk Analysis, Boston, Mass.) (copy available at Columbia Journal of Environmental Law).

19. Slovic, *supra* note 14, at 403.

20. *Id.* at 411.

21. *Id.* at 412.

Given these problems and opportunities, the comparative risk concept is now evaluated to determine if it can be responsibly used to solve the persistent problems of risk decisionmaking—prioritization of risks for regulatory action and the setting of risk limits in agency and judicial proceedings.

IV. COMPARATIVE RISK FOR SETTING REGULATORY PRIORITIES

A regulatory agency must comply with its statutory mandate. The numerous health, safety and environmental statutes contain diverse provisions and directions but commonly delegate four essential functions to the agencies for implementation:

(1) to identify and select hazards for regulatory management;
(2) to make the necessary findings of fact about these hazards in order to support regulatory actions (e.g., using risk analysis and other means);
(3) to evaluate the available regulatory options; and
(4) to choose and define the regulatory option and the risk limit to be achieved.

The comparative risk concept is of obvious relevance to the selection of hazards for regulation, the first function, and the setting of the risk limit, the fourth function (to be discussed in a subsequent section). In selecting hazards for regulation, comparative risk can be used as a method for screening a multitude of hazards that have been identified, and thereby enable an agency to prioritize these hazards according to their respective risk attributes, and select some for regulatory action on the basis of their risk significance.

At the outset, it should be recognized that such prioritization on the basis of risk attributes will be a rough estimation, since the agency has not done risk analysis and has a very incomplete data base at this early point in the regulatory process.

Another condition that should be noted at the outset is that use of a comparative risk approach for screening and prioritization may involve matching the hazards and their risk attributes against other known or familiar risks, but will more likely involve a variation on this theme—the comparing of each identified hazard and its risk attributes without reference to any tabulation of any other risks. Thus, the comparative risk approach for prioritization is transformed into a rank ordering of identified hazards and risk attributes for agency use in choosing its regulatory priorities.

Certain statutes restrict this first regulatory function by precluding agency choice of which hazards to regulate and thereby make any use of comparative risk methods moot. This is done by those statutes which require agencies to review all new product applications, as in the case of new drugs, food additives, pesticides and toxic chemicals. By eliminating agency discretion to choose which products to review for risks and possible standard-setting, these laws preclude use of regulatory prioritization methods such as the comparing of risks.[22]

Other types of statutes also restrict the first regulatory function by setting the agency's priorities, either mandating or emphasizing agency action on several specific hazards. For example, the Clean Air Act requires the Environmental Protection Agency (EPA) to list and regulate "ambient air pollutants" and "mobile source" pollutants with strong legislative history and statutory language emphasizing EPA action on several specific pollutants designated by Congress.[23]

Nevertheless, most statutes do not restrict the first regulatory function and afford agencies broad discretion to prioritize risks for regulatory actions, whether by comparison of risk or other methods. For example, other sections of the same Clean Air Act call for EPA listing and regulation of "hazardous air pollutants" and "stationary sources" of air pollution, without narrowing EPA discretion and choice and without providing any statutory obstacle to EPA's use of the comparative risk concept.[24]

Given the discretion afforded by most statutes for choosing among a universe of hazards for regulatory action, agencies have

22. For example, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) provisions on pesticide registration at 7 U.S.C. § 136a (1982 & Supp. IV 1986).

23. The Senate subcommittee report accompanying the 1970 amendments to the Clean Air Act, 42 U.S.C. §§ 7401-7462 (1982 & Supp. III 1985), identified several pollutants as broad threats to national health and recommended EPA regulation by means of national ambient air quality standards under § 108, 42 U.S.C. § 7408 (sulfur oxides, carbon monoxide, hydrocarbons, photochemical oxidants, fluorides, nitrogen oxides, polynuclear organic matter, lead and odors). 1 W. RODGERS, ENVIRONMENTAL LAW: AIR AND WATER § 3.7 at 240-41 (1986). Section 7422 of the Act designates radioactive pollutants, cadmium, arsenic and polycyclic organic matter for EPA to consider regulating under section 7408 (national ambient air quality standards) or section 7412 (hazardous air pollutant standards). Section 7521 designates carbon monoxide, hydrocarbons and nitrogen oxides for EPA regulation as moving source pollutants.

24. *See* 42 U.S.C. §§ 7411(b) (stationary sources), 7412 (hazardous air pollutants) (1982).

devised and used various types of screening or prioritization methods. Some of these methods involve risk comparisons.

In Congressional hearings on Congressman Don Ritter's proposed Comparative Risk Assessment Bill,[25] representatives of several agencies were asked the same questions: "Considering that your resources are limited, how do you determine the priority by which issues are addressed in the regulatory decision process? Is risk assessment or any other method used in this ranking process?"[26]

The Occupational Safety and Health Administration (OSHA) set forth its framework for comparing cancer risks and setting its regulatory priorities, in which the following factors are considered in ranking the cancer risks:

> (1) The estimated number of workers exposed;
> (2) The estimated levels of human exposure;
> (3) The levels of exposures to the substance which have been reported to cause an increased incidence of neoplasms in humans, animals, or both;
> (4) The extent to which regulatory action could reduce not only risks of contracting cancer but also other occupational and environmental health hazards . . . .[27]

Dr. Bailus Walker, for OSHA, explained that the resultant "priority list will obviously determine only the approximate order in which rulemaking shall proceed," and asserted that given technical uncertainties, "any priority list . . . cannot involve a strict numerical ranking scheme."[28] He explicitly rejected the view of several other witnesses before the hearing committee—that cost factors (instead of health risk) be compared in prioritizing for regulatory action—as being impractical given data and resource constraints and the controversial, inaccurate nature of cost estimates and comparisons which "would produce numbers that are so highly speculative as to be essentially meaningless for comparison purposes."[29] Walker also expressed OSHA's opposition to using cost factors for prioritization on other grounds as well: that

25. H.R. 4939, 96th Cong., 2d Sess. (1980).

26. *See, e.g., Comparative Risk Assessment: Hearings Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 96th Cong., 2d Sess. at 437, 506, 519, 551 (1980) (responses by representatives of Food and Drug Administration, Occupational Safety and Health Administration, Consumer Product Safety Commission and Environmental Protection Agency) [hereinafter *Comparative Risk Hearings*].

27. *Id.* at 506.

28. *Id.*

29. *Id.* at 507.

OSHA must deal with many types of health risks besides cancer, and that such ranking methods leave unanswered how one quantitatively evaluates different types of health risks (e.g., mortality, morbidity) on a relative basis.[30]

The Consumer Product Safety Commission (CPSC) system was described by Dr. Peter Preuss.

> We consider several factors in setting priorities: frequency and severity of injuries; causes of these injuries; the relative cost and consumer benefits of [CPSC] actions; the vulnerability of those likely to be injured; the possibility of chronic illness or future injuries; and probability of exposure to the risk.
>
> These criteria are used to prepare our annual priority list . . . .
>
> There are many questions that remain unanswered, which make comparative assessment of risk extremely difficult. Even if we are able to assess different types of risks accurately, we would still have difficulty deciding among them. The choices to be made could be, for example, among: (a) 0.1 percent probability of electric shock; (b) 75 percent probability of severed fingers; (c) 0.001 percent probability of cancer; (d) 50 percent probability of fire . . . (e) 0.00001 percent probability of birth defects . . . or (f) 100 percent probability of a bruised knee.[31]

Preuss also pointed to other problems with risk comparisons, including the uncertainties, variable assumptions used and the agency's view that consumer risks which arise from convenience and luxury products should be treated differently than risks arising from other types of products. He concluded that "we see risk assessment and comparative risk assessment as tools which can be used along with many others to reach regulatory decisions. We do not see them as ultimate determinants, nor even as tools that are useful in all cases at all times."[32]

Other agencies also presented their prioritization methods, including the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). FDA's elaborate scheme for comparing risks to set priority rankings was notably different from that of other agencies in that it incorporated the views of consumer and other public interest groups, thereby expanding the concept of comparative risk assessment to include public per-

30. *Id.* at 507-08.
31. *Id.* at 511-12.
32. *Id.* at 512.

ceptions and attitudes about risk.[33] In stark contrast to FDA's detailed and sensitive approach was EPA's evasiveness and failure to respond to the Committee's questions on how it set its regulatory priorities, evincing its lack of any policy for establishing priorities.[34] EPA is now attempting to remedy this situation by conducting a "Comparative Risk Project" for ranking risks subject to its regulatory jurisdiction, with the intention of using the results to set its funding and resource priorities.[35]

Although these agency systems have undoubtedly been modified since 1980, when they were described to the House Subcommittee, the major issues raised at that time about the usefulness of comparing risks to set priorities have not been publicly resolved and presumably persist today.

These issues include (1) technical uncertainty about the health risk attributes, since in-depth regulatory research and risk analysis (with public comments and industry inputs) have not been done at this early stage of regulation—thereby militating against any quantitative comparison and rankings which would be relatively conclusive or defensible; (2) inability to establish a common valuation scale or system for priority-ranking different types of risks with their different probabilities of manifestation and their differing health significance attributes, such as pain and suffering, job disability, hospitalization, impairment of function, death, etc.; (3) societal values and attitudes about risks, which may confound purely quantitative approaches for ranking risk by incidence and severity, such as the voluntariness of exposure, the importance of the source of the risk to the person at risk, the negligent or willful behavior of the risk generating organizations, and whether the availability of self-help or compensatory options to persons at risk should diminish agency concern for the risk; and (4) the technology-forcing functions required by certain statutes which are not related to any ranking of health risks.

33. *Id.* at 437. FDA's elaborate project priorities and methods are detailed at 438-89.

34. *See id.* at 542-51.

35. [Current Developments] Env't Rep. (BNA) 2203 (April 11, 1986). The project produced a report in February 1987. *See* EPA, UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS OVERVIEW REPORT (1987); *E.P.A. Report Says Agency Focuses on Lesser Problems*, N.Y. Times, Feb. 19, 1987, at B6, col. 5.

The agency also began re-examining the hazard ranking system used to develop the National Priorities List under the Comprehensive Environmental Response Cleanup and Liability Act. [Current Developments] Env't Rep. (BNA) 707 (Sept. 12, 1986).

Finally, as the testimony of industrial officials and economists ardently advocated, risks could also be compared and prioritized by their economic attributes. Although this approach would provide a common metric (dollars) for valuing each risk and for estimating the cost-effectiveness of regulatory actions, it has been repudiated by OSHA, FDA and CPSC spokesmen on several grounds: it would load arbitrary dollar valuations of different types of risks onto uncertain health risk estimates; and it would transform Congressional mandates for health risk reduction and technology-forcing into mandates for minimizing the costs of risk regulation.

From the foregoing, it appears that agencies not constrained by statutory language develop several methods and criteria, including risk comparison, to establish regulatory priorities but are reluctant to rely on risk comparison as a conclusive criterion, using it only as one of several methods for eventually setting their regulatory priorities, or for later defending their choices of risks.

V. Setting Risk Limits in Regulatory Actions

A. Background

Agencies face the risk limit issue in two decisionmaking contexts. In the standard setting context, the agency has selected a risk for regulatory action, measured it, considered several regulatory options and their economic and other implications, and finally confronts the issue of the risk limit—the stopping point for its risk reduction standard.

In the permit or product approval context, the agency has evaluated a petition or application for approval of an activity (e.g., construction of a power plant) or product (e.g., a pesticide) and is deliberating about the terms and conditions to be imposed on the applicant. Some of these terms will be designed to control the risk level of the proposed activity or product and, in some instances, the agency can do this by simply incorporating existing standards it has already set in other proceedings. Often, however, no generic standards are suitable or available for incorporation in the permit as limiting conditions, and the agency must then grapple with the problem of setting ad hoc or special risk-limiting terms to conclude its decision process.

Surprisingly little is known about how agencies actually set risk limits in these two regulatory contexts, despite the volumes of

published materials on uses of cost-benefit and risk-benefit analysis in regulatory decisionmaking. According to Rodricks:

> Although there have been numerous studies of . . . most elements of the risk assessment-risk management process, at least one element appears to have escaped detailed analysis: the determination of whether a given predicted risk poses a significant threat to the public health and of the extent to which risk reduction is needed to achieve public health protection.[36]

But this void is now being filled. Several policy and legal analyses of agency methods for establishing what constitutes a "significant risk" have been published recently.[37] These studies have been stimulated by the Supreme Court's 1980 decision which invalidated OSHA's revised benzene standard because the agency had not established that benzene, already subject to an earlier OSHA standard, still posed a "significant risk" to workers and merited the more stringent revised standard.[38]

Several studies have also evaluated the "de minimis risk" concept and its proposed and actual uses in agency decisionmaking to set risk limits.[39] "De minimis risk" has been defined as a risk level so trivial that it does not merit regulatory attention.[40] The concept has therefore been proposed as a means for determining what is not a significant risk and has been vigorously promoted by the FDA as a rationale for approving the use of carcinogenic food and cosmetic additives (e.g., use of methylene chloride for coffee

36. J. Rodricks, S. Brett & G. Wrenn, Significant Risk Decisions in Federal Regulatory Agencies 1 (unpublished paper) [hereinafter Rodricks] (copy may be requested in writing from ENVIRON Corporation, 1000 Potomac Street, Washington, D.C. 20007).

37. Cross, *Beyond* Benzene: *Establishing Principles for a Significance Threshold on Regulatable Risks of Cancer*, 35 EMORY L.J. 1 (1986). *See also* Latin, *The "Significance" of Toxic Health Risks: An Essay on Legal Decisionmaking under Uncertainty*, 10 ECOLOGY L.Q. 339 (1982).

38. Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980).

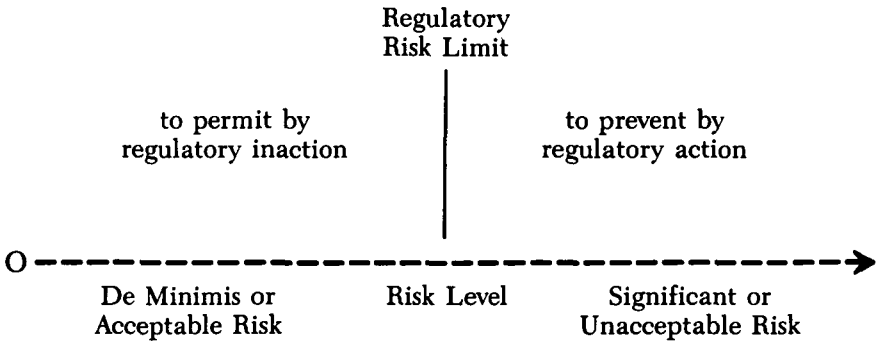
39. *See* FIKSEL & BARAM, *supra* note 1; Mumpower, *supra* note 11; Cross, *supra* note 37. *See also* Spangler, *The Need for De Minimis Risk Standards in Regulatory Decisionmaking: An Individual or Societal Risk Concept?* in ENVIRONMENTAL HEALTH RISKS: ASSESSMENT AND MANAGEMENT 205 (R.S. McColl ed. 1987); M. Spangler, A Summary Perspective on NRC's Implicit and Explicit Use of De Minimis Risk Concepts in Regulating for Radiological Protection in the Nuclear Fuel Cycle (unpublished paper) (copy may be requested in writing from Miller B. Spangler, Special Assistant for Policy Development, United States Nuclear Regulatory Commission, Washington, D.C. 20555).

40. Alabama Power Co. v. Costle, 636 F.2d 323, 360 (D.C. Cir. 1968). *See infra* note 56 and accompanying text.

decaffeination)[41] which pose a lifetime risk of one in a million or less for cancer.[42] This FDA attempt to avoid the zero cancer risk mandate of its governing statute's "Delaney Clause" by formulation of a de minimis risk approach has recently been denied by a federal Court of Appeals as being contrary to the strict statutory language of the Delaney provision.[43]

B. Agency Efforts

"Significant risk" and "de minimis risk" concepts essentially represent the two sectors of any particular risk, the former being the sector to be regulated or prevented, the latter being the sector to be unregulated or permitted. Because of differing statutory nomenclature, some analysts and agencies use the terms "unacceptable risk" and "acceptable risk" as synonyms for "significant risk" and "de minimis risk," respectively.[44] Thus, any particular risk would accordingly be divided into two sectors, as follows:



41. *See Methylene Chloride: FDA's De Minimis Tested*, ENVIRON REPORT 2 (Fall 1986) (copy may be requested in writing from ENVIRON Corporation, 1000 Potomac Street, Washington, D.C. 20007).

42. *See* Cooper, *Stretching Delaney Till It Breaks*, 9 REGULATION 11 (Nov./Dec. 1985).

43. Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987). Petitioners challenged the FDA's decision to list two color additives, Orange No. 17 and Red No. 19, based on quantitative risk assessments indicating that cancer risks presented by these dyes were trivial. The decision hinged on construction of the Delaney Clause for color additives, 21 U.S.C. § 376(b)(5)(B), one of three Delaney Clauses in the Food, Drug and Cosmetic Act.

44. The term "unreasonable risk" is used in section 2605(a) of the Toxic Substances Control Act, 15 U.S.C. §§ 2601-2654 (1982 & Supp. IV 1986), and is yet another synonym for significant or unacceptable risk. For a discussion of the factors considered in deciding whether a chemical poses an unreasonable risk, see J.C. DAVIES, S. GUSMAN & F. IRWIN, DETERMINING UNREASONABLE RISK UNDER THE TOXIC SUBSTANCES CONTROL ACT (1979) (The Conservation Foundation, Washington, D.C.).

Agencies have not coordinated their respective approaches, nor have they acted with internal consistency, in defining these two risk sectors and determining where the risk limit should lie. In defining the significant or unacceptable risk sector, agencies are directed by differing statutory criteria and therefore reach differing outcomes. But in defining the acceptable (or de minimis) risk sector, agencies have recently adopted various simplistic formulations, such as a 1×10^{-6} lifetime risk of cancer, to establish the risk limit. These formulations have been made without the guidance of any statutory criteria. No statutes directly define de minimis risk, probably because Congress assumed that this risk sector would be defined as a consequence of agency determination of significant risk in accordance with statutory language.

This results in a confusing set of outcomes across the several agencies and within each agency. EPA, for example, operates under the inconsistent demands of numerous regulatory programs. According to Cross:

> Unfortunately, to date the various federal health and safety agencies have adopted only a haphazard, disorganized response to both the *Benzene* decision and the Court's rationale. The result has been an inconsistent pattern of regulation which may be questioned on both legal and public policy grounds. When agencies have used a significant risk cutoff to guide regulation, they have been unable to select even a consistent measure of risk.[45]

For example, Rodricks reports de minimis determinations for lifetime cancer risk by the FDA of one in 14,000 (PCBs in fish)[46] and one in one million (1×10^{-6}) (animal drug residue, methylene chloride decaffeination under Delaney clause);[47] EPA pesticide determinations usually at 1×10^{-6} but running to 1×10^{-4} when benefits were large, and to levels beyond 1×10^{-6} when benefits were seen as negligible;[48] EPA carcinogenic air pollutant determinations usually at 1×10^{-5} but running to 1×10^{-3} for radionuclides and benzene;[49] EPA drinking water pollutant

45. Cross, *supra* note 37, at 3-4 (footnotes omitted).
46. Rodricks, *supra* note 36, at 6.
47. *Id.* at 4.
48. *Id.* at 6-7.
49. *Id.* at 10-12; *see also* [Current Developments] Env't Rep. (BNA) 616 (Aug. 10, 1984) (EPA table of cancer risks for airborne toxics).

determinations at zero exposure;[50] and EPA hazardous waste cleanup determinations at Superfund sites ranging from 1×10^{-7} to 1×10^{-4}.[51]

This disarray has been independently confirmed by Cross:

> The preceding discussion demonstrates the tremendous variance in agencies' determinations concerning de minimis risk levels that do not warrant regulation. The Consumer Product Safety Commission, for example, will regulate a risk of three chances in one hundred thousand, while OSHA will accept risks as high as eight chances in one thousand, or almost three hundred times the threshold level regulated by the CPSC. Similarly, the Nuclear Regulatory Commission will accept a risk more than one hundred times greater than will the Food and Drug Administration. . . . The EPA permits a residual risk from uranium tailings that is more than a thousand times the risk it allows under the Clean Water Act. The risk level regulated by the EPA under a single statute, FIFRA, has varied by two orders of magnitude in recent years . . .
>
> . . . [T]he differences observed in practice are not based upon any explained distinction in statutory mandates, but rather appear haphazard. . . . In sum, at the present time, there appears to be no coherent significant risk policy in federal regulatory agencies.[52]

This haphazard or ad hoc approach to defining significant and de minimis risk sectors, or risk limits, damages agency credibility and makes the whole enterprise look as arbitrary as earlier agency uses of cost-benefit analysis on an ad hoc basis.[53] Clearly, a principled approach, embodied in a formal, generic policy, for making both significant and de minimis risk determinations is needed. Such an approach would provide for internal consistency within

50. Rodricks, *supra* note 36 at 12; *see also* [Current Developments] Env't Rep. (BNA) at 976 (Oct. 24, 1986) (risk from drinking water set at zero).

51. *See* Rodricks, *supra* note 36, at 12.

52. *See* Cross, *supra* note 37, at 43-44. *Contra* Travis, Richter, Crouch, Wilson & Klema, *Cancer Risk Management*, 21 ENVT'L SCI. & TECH. 415, 420 (1987), who find "the history of federal decision making indicates that all agencies are fairly consistent in their implicit definitions of . . . de minimis risk levels." They note that agencies always regulate chemicals posing an individual risk of death greater than 4×10^{-3} and, with the exception of one FDA decision, never regulate chemicals posing a risk of less than 1×10^{-6}. *Id.* at 418. They also find some correlation between the size of the population exposed and the de minimis risk limit. *See id.* For example, for small exposed populations, regulatory action is never taken for risks below 1×10^{-4}, but for exposures affecting the entire U.S. population, the de minimis risk level is 1×10^{-6}. *Id.*

53. *See, e.g.*, Baram, *supra* note 8, at 519-20 (both EPA and NRC have applied cost-benefit analysis inconsistently).

each agency and foster inter-agency consistency to the extent permitted by the differing statutory mandates of each agency.[54]

Several federal court decisions have promoted agency development and use of methods for setting risk limits in regulatory decisions. For example, in *Alabama Power Co. v. Costle*,[55] Judge Leventhal considered EPA's prospective exemption of certain categories of stationary sources of air pollution from its regulatory requirements aimed at prevention of significant deterioration of air quality. Judge Leventhal, a noted proponent of agency rules of reason, stated his view that:

> Categorical exemptions may also be permissible as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered *de minimis*. . . . [T]he law does not concern itself with trifling matters, and this principle has often found application in the administrative context. Courts should be reluctant to apply the literal terms of a statute to mandate pointless expenditures of effort. . . . The ability . . . to exempt *de minimis* situations from a statutory command is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design.
>
> Determination of when matters are truly *de minimis* naturally will turn on the assessment of particular circumstances, and the agency will bear the burden of making the required showing. But we think most regulatory statutes, including the Clean Air Act, permit such agency showings in appropriate cases.[56]

The court thus accepted the de minimis risk rationale, although it found the particular exemptions made by EPA in the matter being reviewed to be invalid.

54. For recent recommendations as to a generic approach, see FIKSEL & BARAM, *supra* note 1; Cross, *supra* note 37. Traditionally, the Nuclear Regulatory Commission has surpassed all other agencies in setting forth generic principles and policies. Statutory language may preclude agency adoption of a de minimis risk approach. Public Citizen v. Young, 831 F.2d at 1108 (Delaney Clause for color additives does not permit FDA adoption of de minimis risk method).

55. 636 F.2d 323 (D.C. Cir. 1979).

56. 636 F.2d at 360-61 (footnotes omitted). *See also* Monsanto v. Kennedy, 613 F.2d 947, 954 (D.C. Cir. 1979) (FDA has power under de minimis doctrine to exempt from regulation acrylonitriles that diffuse in trivial amounts into foods). *Cf.* Environmental Defense Fund v. EPA, 636 F.2d 1267, 1283 (D.C. Cir. 1980) (disallowing de minimis exception under Toxic Substances Control Act for materials containing less than 50 parts per million PCB when far smaller concentrations shown to be toxic); Aqua Slide'n Dive v. Consumer Product Safety Commission, 569 F.2d 831, 842 (5th Cir. 1978) (argument that extremely remote risk of paraplegia from swimming pool slides is a "reasonable risk;" court invalidates CPSC regulation requiring warning signs on slides as not "reasonably necessary" to reduce the risk).

One year after *Alabama Power Co. v. Costle*, the Supreme Court drove the point home by invalidating OSHA's revised benzene standard because the agency had not demonstrated that the standard would prevent a significant risk. The plurality opinion in this case, *Industrial Union Department, AFL-CIO v. American Petroleum Institute*,[57] thereby stands for the proposition that OSHA is required to make a threshold finding of fact that a significant risk is present in the work place before the agency can promulgate a valid standard for reducing this risk.[58] In accordance with the significant risk/de minimis risk dichotomy discussed earlier, the Supreme Court has essentially required OSHA to factually establish that any risk it intends to regulate is not a de minimis risk. As a practical matter, other agencies must now heed this proposition unless their authorizing statute requires zero risk regulation or otherwise precludes agency determination of a significant risk level on a discretionary basis, as in the case of the FDA's Delaney Clause.

No court has yet offered clear guidance to the agencies as to any quantitative measure for marking the division between de minimis and significant risks, although in the benzene case, the Supreme Court did go so far as to opine that the dividing line or risk limit for a lifetime occupational cancer risk lies somewhere between 1×10^{-3} and 1×10^{-9}.[59] Rodricks has found that since the date of this decision, "OSHA has not judged any occupational carcinogenic risk to be clearly insignificant, but has not sought to force predicted lifetime risks below *ca.* 10^{-3}. It appears that, in least in principle [sic], OSHA is prepared to find some level of occupational risk insignificant."[60]

57. 448 U.S. 607, 642 (1980).

58. *Cf.* Public Citizen v. Young, 831 F.2d 1108, discussed *supra* note 43.

59. *Id.* at 655. The Court of Appeals in Public Citizen v. Young also deliberately avoided setting a "dividing point between *de minimis* and other risks." 831 F.2d at 1112 n.4.

60. Rodricks, *supra* note 36, at 19. Rodricks believes that this risk limit may be due to several factors in addition to the Supreme Court's ambiguous placement of the risk limit as being somewhere between 1×10^{-3} and 1×10^{-9}; namely that a risk of 1×10^{-3} is "low compared to other fatality hazards in jobs commonly thought of as 'safe,' " *id.* at 14, and that the "feasibility criteria" in OSHA's statute for reducing risk militate against setting tougher standards. *Id.* at 17. *See* Public Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1502 (D.C. Cir. 1986): "OSHA . . . found that EtO exposure at 1 ppm (12-23 excess deaths estimated [per 10,000 workers]) poses a significant risk itself. The agency set the PEL [standard] at 1 ppm, however, not because no excess deaths would occur at that level, but because it could not show that any lower . . . limit would be feasible."

Thus, the problem of developing a principled approach to defining the risk limit remains a challenge for the federal agencies—whether in the context of a specific decision process or in the context of developing a consistent agency or inter-agency policy.

The comparative risk concept has recently been proposed, and in some instances used, by agencies to support risk limit determinations in various regulatory proceedings. This concept, and the opportunities and problems it presents, will now be discussed.

C. Comparative Risk Concepts in Use

At this time, no federal agency has set forth a formal regulatory policy for generic use of a comparative risk method to set consistent limits in its regulatory proceedings. However, EPA has developed risk comparison data for several of its regulatory programs,[61] discussed its potential uses and used risk comparisons to communicate with the public about new problems such as radon.[62] Two agencies, OSHA and the NRC, now regularly use risk comparisons as one of several supports for the risk limits they set in regulatory proceedings.

OSHA now considers five factors in establishing whether a risk is significant, according to a recent report: the quality of the underlying data, the "reasonableness" of the risk assessment, the statistical significance of the findings, whether the risk at issue is material and the numerical significance of the risk relative to other occupational risks.[63]

Obviously, the fifth factor involves risk comparisons, which, according to Rodricks, use as "benchmarks" the fatality rates in certain occupations compiled by the Bureau of Labor Statistics.[64] The fatality rates arise from many different types of risks (e.g., mining fatalities from explosions, gas, structural failures, flooding, accidents, etc.). Thus, OSHA's consideration of the risk limit to set for cancer from toxic chemicals in a particular type of work place will be based on five factors, one of which will be a numeri-

61. *See Summary of Data on Specific Pollutants and Cancer Risk Estimates Excerpted from EPA Draft Study on Air Toxics Problem in United States*, [Current Developments] Env't Rep. (BNA) 616-18 (August 10, 1984)

62. *See Radon: Threat Is Real, but Scientists Argue Over Its Severity*, N.Y. Times, Sept. 2, 1986, at C1, col. 1; *Environmental Authorities Must Increase Focus on Individuals to Bring Progress, Russell Says*, [Current Developments] Env't Rep. (BNA) 917 (Oct. 17, 1986).

63. *OSHA Official Outlines Agency's Steps in Deciding if Significant Risk Exists*, 16 Occupational Safety and Health Reporter (BNA) 599 (Nov. 5, 1986).

64. *See* Rodricks, *supra* note 36, at 15-16.

cal comparison of the cancer fatality rates associated with the chemical with death rates arising in very different occupational contexts from very different types of risks.

Rodricks describes the growing reliance of EPA and NRC on these same occupational fatality rates for evaluating, by means of comparisons, whether certain risks being considered for regulation by EPA and NRC are significant.

> EPA and the Nuclear Regulatory Commission (NRC), for example, have proposed to set federal radiation standards using as a yardstick the fatality rates prevalent in industries commonly considered to be relatively safe.
>
> In its radiation protection proposal, EPA noted that "the risk of job-related accidental death in the safest of all major occupational categories, retail trades, [was] an annual death rate [of] 60 per million workers in 1975." This risk equates to a 45-year worklife risk of 2.7 in 1,000. The Agency based its proposed radiation protection guidelines on its finding that radiation risks of a magnitude similar to 3 in 1,000 "do not appear unreasonably high" because "[t]hey are comparable to risk of accidental death in the least hazardous occupations."
>
> In a similar vein, NRC's recent radiation protection proposal follows the approach recommended by the International Commission on Radiological Protection . . . which developed its guidelines by "comparing [radiation] risk with that of workers in industries . . . which are recognized as having high standards of safety." As NRC pointed out, in such " '[s]afe' industries . . . average annual mortality due to occupational hazards does not exceed 10^{-4} . . . ." This annual rate amounts to a 45-year lifetime risk in excess of 4 in 1,000. Like EPA, NRC proposed standards on the basis that occupational mortality risks due to radiation are "acceptable" if kept at or below this "safe industry" risk level.[65]

The NRC has also published proposed rules and a policy statement in 1986 which express its reliance on risk comparisons for setting limits on its regulatory actions.[66] For example, in its policy statement on how it will make decisions on the exemption of certain wastes from disposal in licensed low level radioactive waste disposal facilities, NRC has set forth several criteria, including one that provides "the maximum expected effective dose

65. *Id.* at 15, 17.

66. Radioactive Waste Below Regulatory Concern; Policy Statement, 51 Fed. Reg. 30839 (Aug. 29, 1986) (to be codified in 10 C.F.R. § 2 app. B.); Safety Goals for the Operations of Nuclear Power Plants; Correction and Republication of Policy Statement, 51 Fed. Reg. 30028 (Aug. 21, 1986).

equivalent to an individual member of the public does not exceed a few millirem per year for normal operations and anticipated events."[67] Discussion of this criterion is focused on a one millirem per year risk limit, which in turn is justified by a comparison of this risk limit to various EPA standards (which establish a 25 millirem per year risk limit for radioactive air pollution and the uranium fuel cycle), to natural background levels of human exposure (100 to 120 millirem per year), to Federal Radiation Council guidance (500 millirem per year) and to various British and Canadian standards.[68] Thus, comparative risk will be used to support NRC determinations of radioactive wastes which fall "below regulatory concern" because they pose insignificant or de minimis risks.

NRC's policy statement on Safety Goals for the Operation of Nuclear Power Plants[69] is also replete with uses of comparative risk to set risk reduction controls on reactor operation. After assuring the public "that no death attributable to nuclear power plant operation will ever be 'acceptable' " and drawing the distinction that it "is discussing acceptable risks, not acceptable deaths," NRC sets forth its "qualitative safety goals," including one that "societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies . . . ."[70]

NRC also provides its "quantitative objectives," which "are to be used in determining achievement of [its] safety goals:"

> —The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent . . . of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.
> —The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent . . . of the sum of cancer fatality risks resulting from all other causes.[71]
>
> . . . .
>
> The Commission believes that this ratio of 0.1 percent appropriately reflects both of the qualitative goals—to provide

67. 51 Fed. Reg. at 30844.
68. *Id.* at 30845.
69. 51 Fed. Reg. 30028.
70. *Id.*
71. *Id.* at 30028-29.

> that individuals and society bear no significant additional risk.[72]

In separate views, Commissioners Asselstine and Bernthal took issue with various aspects of the NRC policy statement. Bernthal focused on whether the NRC approach would provide the public with "clear, unambiguous, practical safety objectives" that would answer the question "how safe is safe enough."[73] He concluded that "the question remains unanswered" despite the comparative risk approach used, because the risks are not viewed as comparable by the public[74] and because the 0.1 percent goals do not include population density considerations.[75]

D. Judicial Review

Only a few agency decisions based in part on risk comparisons have been tested in the courts. Despite vigorous attacks on agency uses of comparative approaches to establish risk limits in these regulatory decisions, the courts have approved such uses of risk comparison.

In *San Luis Obispo Mothers for Peace v. NRC*,[76] petitioners argued that NRC had acted arbitrarily in issuing low and full power operating licenses to the Diablo Canyon power plant. Petitioners focused in particular on NRC's refusal to hold a hearing to consider earthquake events and their potential effects on emergency response plans for public safety,[77] and argued that this refusal was arbitrary and irrational in that NRC had considered other natural phenomena, such as volcanos, tornados, hurricanes, fog and heavy rain, which could also have potential effects on emergency

72. *Id.* at 30030.

73. *Id.* at 30033.

74. "It is unrealistic for the Commission to expect that society, for the foreseeable future, will judge nuclear power by the same standard as it does all other risks." *Id.*

75. [A] power plant could be located in Central Park and still meet the Commission's quantitative offsite release standard. . . .

> . . . [T]he Commission's standards should preserve the important principle that site-specific population density be quantitatively considered . . . e.g., by requiring that for the *entire* U.S. population, the risk of fatal injury . . . should not exceed some appropriate specified fraction of the sum of the expected risk of fatality from all other hazards to which members of the U.S. population are generally exposed.

Id.

76. 789 F.2d 26 (D.C. Cir. 1986), *cert denied*, 107 S. Ct. 330 (1986).

77. *Id.* at 29.

plans and public safety.[78] NRC's defense rested on the very low probability of an earthquake initiating or occurring contemporaneously with a plant accident so as to interfere with an emergency response.[79] Earthquakes as a risk factor were therefore essentially insignificant or de minimis.

A majority of the court held that petitioners failed to establish that NRC's refusal to require emergency response plans to consider earthquakes was arbitrary or irrational. The majority accepted NRC's logic that the agency should consider only those natural phenomena that "frequently occur" at a particular site and that the phenomena to be considered in licensing a particular plant will accordingly vary from site to site (e.g., snow to be considered for a plant in Pennsylvania, but not for a plant in Florida).[80] It then found sufficient support in the record of the licensing proceeding for NRC's exclusion of earthquakes:

> [I]t is sufficient that the record establishes that fog is 24,200 times more likely to occur, and rain 6,875 times more likely to occur, at Diablo Canyon than is a major earthquake. . . . Under these circumstances, the Commission certainly drew a rational distinction between rain and fog, on the one hand, and earthquakes, on the other. Given the relative probabilities, this court cannot conclude that the Commission's decision was arbitrary and capricious.[81]

Four judges joined in vigorous dissent on several grounds: first, that the NRC had not " 'articulated a satisfactory explanation for its action including a "rational connection between the facts found and the choice made," ' " particularly since the agency's earlier "design proceedings centered on the plant's proximity to an active earthquake fault;"[82] second, that the majority had effectively gutted the emergency planning regulations by "downplaying the frequency of earthquakes by multiplying their probability by the probability of a radiological accident" to arrive at a de minimis frequency finding for earthquakes, instead of dealing with the probability of the "complicating event" (the earthquake) alone;[83] and finally, that the NRC had not adequately defined

78. *Id.* at 40-42.
79. *Id.* at 37-40.
80. *Id.* at 42.
81. *Id.*
82. *Id.* at 47.
83. *Id.* at 50. *See also* discussion at 55 (citation omitted): "By automatically multiplying the 1 in 100,000 chance of a nuclear accident by the likelihood of any natural hazard oc-

"frequently occurring" natural hazards, that "by failing to . . . describe where the cut-off point between frequently and infrequently occurring phenomena might lie—the Commission has made it impossible to apply the standard to hazards other than those specifically listed."[84]

Similar results, affirming agency reliance on comparative risk methods to make risk limit decisions, have been reached in Massachusetts courts. In *Town of Brookline v. Commissioner of the Department of Environmental Quality Engineering* (DEQE),[85] Brookline challenged DEQE's decision approving operation of Harvard University's "MATEP" power plant.

DEQE had made this decision after ten years of regulatory hearings and litigation, during which DEQE and state courts had ordered some thirty-five design and operational changes in the MATEP proposal. These prior changes had considerably reduced MATEP risks to human health in the Metropolitan Boston area; but when Harvard submitted its revised plan to DEQE for final approval, DEQE conducted a risk analysis and determined that the plant's operation would still cause up to four cancer deaths in the exposed population of 1.6 million people over the next forty years. Thus, DEQE faced the ultimate problem of determining whether this remaining risk of four lung cancer deaths was too great or significant to permit its final approval of the modified plant proposal.

The agency dealt with the risk limit issue in its final decision process by comparing the MATEP risks with the magnitude of other risks common in society. Using rough comparisons, DEQE determined that the four death risk from the MATEP operation was not unreasonable and approved the plant's operation on this basis, prompting the Brookline appeal. Specifically, the DEQE administrator's final decision addressed the issue: "is the risk posed by MATEP after application of the best available control technology reasonable?" and concluded:

> I adopt the Department staff's approach of determining relative risk as the most sensible and appropriate method of addressing the issue. The Department in all of its regulatory activities . . . is faced with making judgements [sic] based on

curring, the majority reduces all simultaneous occurrences to a 'never-never' land beyond rational planning."

84. *Id.* at 54.

85. 398 Mass. 404, 497 N.E.2d 9 (1986).

> relative risks with or without the benefit of clear numerical standards. . . .
>
> . . . .
>
> Using the Department staff's relative risk method . . . I conclude that a maximum increased risk of lung cancer of zero to four excess cases in a population of 1.66 million persons over a period of 40 years . . . is not unreasonable.[86]

In its appeal to the state's highest court, Brookline argued, among other things, that the agency had exceeded its statutory authority in using a "reasonable risk" criterion and that DEQE had also acted impermissibly under its statutory mandate by comparing MATEP risks to various risks due to other sources and exposure circumstances in order to determine whether the plant's operational risk was reasonable and whether the facility should be approved.[87]

Brookline's argument that DEQE had exceeded its statutory authority by devising and applying a reasonableness test was based on provisions of the state's law and regulations for implementing the federal Clean Air Act. The state law and regulations provided that DEQE disapprove a "new source of air pollution," if it was to (a) cause a nuisance, (b) be potentially injurious to human life or (c) unreasonably interfere with the comfortable enjoyment of life.[88] The court denied this argument:

> The Legislature has granted DEQE broad authority. . . . DEQE thus is charged with evaluating the technical evidence and reaching a decision on the risk attributable to the new source. That decision includes a determination of the boundary within which the risk will be acceptable. . . . "[w]hat may be injurious to life . . . is best left to the DEQE to determine on a case-by-case basis in light of the most current scientific evidence."[89]

The court then proceeded to deal with the other issues "mindful of [its] limited role of review. . . ."[90]

Brookline's argument that DEQE had acted impermissibly in using risk comparisons to reach its final decision was among the several issues then considered. According to Brookline:

86. Medical Area Total Energy Plant, Inc., Application 77-51 at 15-16 (DEQE January 3, 1985) (final decision on remand after hearing).

87. 398 Mass. at 410, 497 N.E.2d at 12.

88. *Id.* at 413 n.12, 497 N.E.2d at 14 n.12.

89. *Id.* at 411, 497 N.E.2d at 13 (citation omitted).

90. *Id.*

DEQE's health expert, Dr. Halina Brown, brought into the proceeding [DEQE final hearing on MATEP] a comparative risk assessment which was not suggested in her pre-filed direct testimony. She sought to justify the four lung cancer deaths . . . by comparing these with existing environmental risks, namely, the risk of contracting cancer from polluted public drinking water and contaminated urban air. Although Dr. Brown conceded on cross-examination that such a risk assessment is not permitted under any environmental laws or programs, nonetheless, in concluding that four lung cancer deaths are acceptable, she compared these deaths with the number of potential deaths which could result from ingesting pollutants in public drinking water at levels allowable under EPA's standards. . . . Dr. Brown recognized that providing drinking water is an activity significantly different from MATEP's electricity generation, in that providing water is an essential public service and standards . . . for public water supply must take account of existing pollution conditions, the technical feasibility of reducing the pollutants . . . and associated costs, in order to [enable] a municipality to continue to provide drinking water to its citizenry. In contrast, the electricity from MATEP is unnecessary since its intended customers can continue to obtain their electrical needs from Boston Electric Company; hence the carcinogenic emissions from MATEP can be avoided without any interruption in essential services.

. . . The Hearing Officer also cast doubt upon the propriety of comparing such risks when she concluded:

> "it is also true that one can certainly not conclude that the toleration of certain level[s] of cancer risk from drinking water, for example, implies that society has tacitly accepted an equivalent risk from other sources or activities."

The Hearing Officer pointed out to Dr. Brown that a problem with her comparative risk analysis is that "the dirtier the area is to begin with, the greater the new sources of pollution that would be allowed," a result at odds with both the federal and state clean air acts . . . [and] directly contrary to the statutory mandate. Dr. Brown appeared to recognize the fallacy of her approach by conceding that her comparative risk assessment probably was a mistake, and was confusing because she did not make decisions by comparing risks anyway. However, she offered no other basis for her "decision" that the four lung cancer deaths attributable to MATEP are acceptable. . . .

Thus, the Deputy Commissioner [of DEQE] followed unlawful procedures in determining that MATEP's predicted deaths

> are acceptable by comparing them to the number of deaths caused by existing sources of pollution.[91]

Brookline's lengthy argument against comparative risk also relied on prior decisions of the Massachusetts courts which had denied arguments that comparative risk should be used to establish the risk limit in regulatory proceedings:

> In reviewing the Massachusetts Department of Public Health's promulgation of an emergency regulation banning the sale of food products containing EDB in amounts greater than a designated level, this Court found that the Department properly relied on its staff's view that "there is no safe level of exposure for a cancer-causing agent" and that genetic changes which result in cancer can occur from only one "hit" of carcinogenic substances. *American Grain Products Processing Institute v. Department of Public Health*, 392 Mass. 309, 324-325 (1984). Nothing in the record of the EDB rule-making proceeding showed that actual deaths would occur if EDB existed in foods in quantities above the proscribed level, rather the record showed that the potential for such deaths existed. An expert for the opponents of the EDB regulation attempted to trivialize the 1 ppb maximum allowable level set by the Department by asserting that such a quantity is:
>
> > ". . . one inch in 16,000 miles, or roughly two-thirds of the distance around the earth. One ppb is one second in 33 years, or one minute in the time elapsed since the birth of Christ. One ppb is one penny in ten million dollars. One ppb is one teaspoon of fertilizer spread evenly over a garden of 5,000 acres. One ppb is equivalent to four drops of water in a filled Olympic-sized pool (64,000 gallons). Or for those of you on a low-carbohydrate diet, one ppb is one crouton in a salad weighing 500 tons."[92]

Brookline then proposed an alternative approach, based on testimony from its own experts which would deny both comparative risk and de minimis approaches:

> MATEP's expert health witness, Dr. Jeffrey Harris, used the same tactic to attempt to trivialize the risk of 4 lung cancer deaths attributable to MATEP by asserting that the risk is equivalent to the risk of cancer to a 40-year-old man who smokes 1.4 cigarettes per year for twenty years. Although Dr. Harris did not offer any evidence to substantiate his compari-

91. Brief for Appellants at 29-32, Town of Brookline v. DEQE, 398 Mass. 404, 497 N.E.2d 9 (1986) (SJC-4135) (citations omitted), filed by Bracken and Baram.

92. *Id.* at 38-39 (quoting American Grain Products Processing Institute v. Department of Public Health, 392 Mass. 309, 330-331, 467 N.E.2d 455, 470 (1984)).

son, such a comparison is wholly inappropriate since smoking is an avoidable risk which the residents of the MATEP impact area can avoid if they choose not to smoke. The Hearing Officer appeared to recognize that comparison of an avoidable risk with an unavoidable risk is inappropriate. Brookline suggests that their expert witness, Dr. David Ozonoff, had the right approach. He testified:

> "If I have a preventable risk, then my wish is to prevent it and not to compare it"
>
> * * * * * * * * * * *
>
> "If 99.5 percent of all cancers are caused by something that I couldn't avoid, that wouldn't excuse my (sic) dealing with the half a percent that I could avoid . . ."
>
> * * * * * * * * * * *
>
> "I think that our society has been fairly clear that there are stricter standards for imposed risks than chosen risks."[93]

Dr. Ozonoff's view was supported by Brookline's medical expert, Dr. Marvin Schneiderman, who, when asked on cross-examination by DEQE's General Counsel whether the plant should be approved if the price for operation was the "human sacrifice" of one person each ten years, replied:

> So, four deaths is not so trivial. Is this hypothetical; are these hypothetical deaths? If we knew specifically who was going to die, we absolutely, certainly, would not permit it to happen. . . . It's only because we don't know who it is and we're fairly certain that it's not going to be ourselves—for what reason I'm not so sure. But we know it's not going to be ourselves. We then sort of say these are acceptable deaths. I don't know who they are acceptable to. They're certainly not acceptable to the person who dies.
>
> . . . [L]ung cancer is a very nasty disease and the survival rates rather poor.[94]

During oral argument, Justices Liacos and Hennessy sharply questioned the comparative risk basis for DEQE's decision on grounds that its use of risk comparisons was ad hoc and not structured or preceded by a generic DEQE regulation and that such comparisons would facilitate the siting of polluting facilities, "stand the Clean Air Act on its head," and lead to giving less regulatory protection to already polluted neighborhoods.

Nevertheless, the court ultimately decided to affirm the DEQE decision because of the "reasonable determination by DEQE that

93. *Id.* at 40 (citations omitted).
94. *Id.* at 45.

the potential risk due to MATEP is within acceptable limits."[95] As for the disputed comparative risk approach, the court found that "[t]his is a decision to be made by the agency within its area of expertise," which it would not scrutinize "except to assure that it is rational and conforms to the law."[96] In so deferring to agency expertise, the court also lent its seal of approval to the general proposition that risk comparisons were a reasonable aid to agency decisionmaking:

> The meaning of an increase in risk of 0.005% is difficult to grasp. . . . DEQE used the comparisons of the MATEP . . . risk and other risks as an aid to comprehension and as a means to understand better the magnitude of risks society generally chooses to accept. Such comparisons are part of a rational method of determining the acceptability of a risk.
>
> We do not share the sense of impending doom that risk comparisons seem to evoke in the Brookline challengers. Brookline's fears that such comparison will lead to approval of ever dirtier emissions are unfounded. We see no reason to presume that DEQE will abandon its statutory role of rationally determining what risks are acceptable to our society under its statutory mandate.[97]

Such federal and state court decisions evidence judicial willingness to accept agency use of risk comparisons as a reasonable and rational basis for setting risk limits in regulatory decisionmaking. Each case involved judicial review of an agency permit decision made after extensive quasi-judicial proceedings by administrators, and each was marked by a dramatic underlying condition—whether a facility already built at substantial cost should be allowed to operate.

Whether similar judicial approval of risk comparisons in standard-setting and other types of regulatory decisions would follow, where the economic stake is not as clearly or dramatically presented, is an open question at this time. Since judicial review of agency quasi-legislative or standard-setting actions is usually less rigorous than that applied to permit and licensing decisions which arise from agency adjudicatory functions, one would expect that risk comparison in standards decisions would also receive favorable judicial responses, unless excluded by statutory language such as that of the Delaney Clause, which has been con-

95. 398 Mass. at 416, 497 N.E.2d at 16.
96. *Id.* at 415, 497 N.E.2d at 15.
97. *Id.* at 415-16, 497 N.E.2d at 15-16.

strued to bar use of a de minimis approach.[98] In an early opinion under the Clean Air Act on EPA's new source performance standard for Portland cement plants as stationary sources of air pollutants,[99] Judge Leventhal set forth a fundamental objection to the use of risk comparisons:

> Petitioners also challenge the cement standards as unfair in light of lower standards mandated for fossil-fuel-fired steam generating power plants and incinerators. They claim that while the cement standard, as expressed in grains of particulates allowed per standard cubic foot of gas (g/scf), requires a reduction to .03, power plants are permitted to reach .12 and incinerators to be at .10. . . .
>
> . . . .
>
> EPA, in response to comments . . . stated . . . "The difference . . . is attributable to the superior technology available therefor."
>
> This statement seems to be supported by the EPA Background Document. . . .
>
> . . . .
>
> The core of our response to petitioners is that the Administrator is not required to present affirmative justifications for different standards in different industries. Inter-industry comparisons of this kind are not generally required, or even productive; and they were not contemplated by Congress in this Act. . . . [T]here is no requirement of uniformity of specific standards for all industries. The Administrator applied the same general approach, of ascertaining for each industry, what was feasible in that industry.[100]

Thus, statutory language of the Clean Air Act has been construed as excluding certain EPA decisions based on inter-industry risk limit comparisons. The Leventhal view may therefore present a formidable obstacle for future advocates of setting standards on the basis of comparison methods, particularly since it has been reaffirmed by the influential D.C. Circuit in rejecting the FDA's use of a de minimis approach some fourteen years later.[101]

Legislative authorization for agency use of risk comparisons could overcome this obstacle and provide more assurance of favorable judicial response. Although no statutes on risk explicitly authorize use of comparative risk methods, some statutes ap-

98. *See supra* note 43.

99. Clean Air Act § 111, 42 U.S.C. § 7411 (1982) (new source performance standards).

100. Portland Cement Association v. Ruckelshaus, 486 F.2d 375, 388 (D.C. Cir. 1973) (standard remanded for other reasons).

101. 831 F.2d 1108. *See supra* note 43.

proach this condition. A Massachusetts statute provides that site selection by a special state board for a hazardous waste facility:

> shall be subject to such limitation with respect to the extent, character and nature of operation thereof as will insure that the facility imposes no significantly greater danger to the public health or public safety from fire, explosion, pollution, discharge of hazardous substances, or other construction or operational factors than the dangers that currently exist in the conduct and operation of other industrial and commercial enterprises in the Commonwealth not engaged in the treatment, processing or disposal of hazardous waste, but utilizing processes that are comparable.[102]

The other statute, the Superfund Amendments and Reauthorization Act of 1986 (SARA),[103] also deals with hazardous waste regulation and provides EPA with a comparative measure for determining "how clean is clean enough" in conducting its remedial actions at hazardous waste sites designated for cleanup.

> [T]he remedial action selected under section 9604 of this title or secured under section 9606 of this title shall require, at the completion of the remedial action, a level or standard of control for such hazardous substance . . . which at least attains . . . legally applicable or relevant and appropriate standard[s] . . . [including] Maximum Contaminant Level Goals established under the Safe Drinking Water Act and water quality criteria established under section 304 or 303 of the Clean Water Act . . . .[104]

102. MASS. GEN. L. ANN., ch. 111, § 150B (1983).

103. Pub. L. No. 99-499, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1613.

104. SARA § 121(d)(2)(A), 42 U.S.C.A. § 9621(d)(2)(A) (West Supp. 1987) ("Degree of cleanup") (citations omitted). "Legally applicable standards" are defined to include standards and criteria under various federal laws administered by EPA, more stringent standards set by state laws, and standards contained in state programs which have been approved by EPA.

In the full, section 121(d)(2)(A) provides:

> With respect to any hazardous substance, pollutant or contaminant that will remain onsite, if—
>
> (i) any standard, requirement, criteria, or limitation under any Federal environmental law, including, but not limited to, the Toxic Substances Control Act, the Safe Drinking Water Act, the Clean Water Act, the Marine Protection, Research and Sanctuaries Act, or the Solid Waste Disposal Act; or,
>
> (ii) any promulgated standard, requirement, criteria, or limitation under a State environmental or facility siting law that is more stringent than any Federal standard, requirement, criteria, or limitation, including each such State standard, requirement, criteria, or limitation contained in a program approved, authorized or delegated by the Administrator under a statute cited in subparagraph (A), and that has been identified to the President by the State in a timely manner,

Thus, use of comparative risk methods for making regulatory decisions on risk limits has been favorably viewed thus far by the judiciary and has been authorized by several legislative actions. Nevertheless, several analytic problems and legal issues are apparent and will undoubtedly be raised in future litigation. Many of these issues were raised in the MATEP case but were not fully considered by the Massachusetts court because of its long standing deference to agency expertise, a tradition which does not prevail in other courts.

E. Problems to Solve

The analytic problems involve, for example, the quality of the estimates of other societal risks which are being compared to the particular risk before the regulatory agencies. These estimates, of variable conclusiveness, arise from very different types of studies—different in terms of the science involved (e.g., toxicology, epidemiology, pharmacokinetics, etc.), the assumptions and causal models used (e.g., as to dose-response relationships), the confidence levels in the results, overall rigor and documentation of the efforts, resources expended and objectivity (e.g., many studies are done for advocacy use). As the *San Luis Obispo Mothers of Peace v. NRC* case demonstrated, even studies arising from the same discipline are hotly contested because of methods and assumptions used.[105] Thus, the risk estimates being compared arise

is legally applicable to the hazardous substance or pollutant or contaminant concerned or is relevant and appropriate under the circumstances of the release or threatened release of such hazardous substance or pollutant or contaminant, the remedial action selected under section 9604 of this title or secured under section 9606 of this title shall require, at the completion of the remedial action, a level or standard of control for such hazardous substance or pollutant or contaminant which at least attains such legally applicable or relevant and appropriate standard, requirement, criteria, or limitation. Such remedial action shall require a level or standard of control which at least attains Maximum Contaminant Level Goals established under the Safe Drinking Water Act and the water quality criteria established under section 304 or 303 of the Clean Water Act, where such goals or criteria are relevant and appropriate under the circumstances of the release or threatened release.

Note that SARA § 122(g), 42 U.S.C.A. § 9622(g), provides for "de minimis settlements" by EPA with "potentially responsible parties" which contributed hazardous substances which are "minimal" in terms of amount and hazardous effects.

105. *See* discussion of San Luis Obispo Mothers for Peace v. NRC, *supra* notes 76-84 and accompanying text. A further example is the lack of consensus among epidemiologists regarding the use of basic statistical tools, such as significance tests and confidence intervals, in assessing results. Thompson, *Statistical Criteria in the Interpretation of Epidemiologic Data*, 77 AM. J. PUBLIC HEALTH 191 (1987). Some authors have been criticized for using confidence intervals to over-interpret skimpy data. *Id.*

from studies which are often not comparable in quality, nor even evaluated as to their merits.

Another analytic problem pertains to whether risks to individuals, populations or both are to be considered and the comparability of the individuals and the populations at risk. In the *Brookline* case, the entire population of Metropolitan Boston would be at risk from breathing the air to be polluted by MATEP. But the other risks used by DEQE for comparison purposes applied only to subsets of this population; for example, the smoking risk pertains only to smokers (and perhaps to those who inhale sufficient "side-stream" smoke), and the risk of drinking polluted water varies from person to person and from town to town in Metropolitan Boston, depending on individual consumption and the various water supply systems being used.

Analytic problems with risk comparison extend further to the types of risks involved and their significance. Comparing deaths from air pollutants that put lung function at risk with deaths from water pollutants that put kidneys at risk involves comparing deaths which arise from different biological processes over different time frames and comparing deaths involving different economic burdens, levels of anxiety, pain, suffering and life support needs.

Finally, there is the issue of whether comparing risks from voluntary activity (e.g., smoking) with risks from imposed activity (e.g., industrial air pollution) is valid from an analytic standpoint, and convincing or acceptable to the public.[106]

Slipshod, ad hoc practices of risk comparison prevail at this time and are likely to increase because most agency proceedings are not governed by rules of evidence which would screen out hearsay and other unreliable types of evidence and because courts which review agency decisions no longer require that the agency decisions be supported by "competent evidence" (or even a "residuum" of competent evidence), the type of evidence required

106. *See* Rodricks, *supra* note 36, at 21.

> It is far from clear how to choose the appropriate background of risk against which to make comparisons. Most analysts, for example, would not compare voluntarily assumed risks to involuntarily assumed risks. . . . [E]ven more difficult is the issue of the relative degrees of reliability in the risk figures being compared. . . . [F]urther attention needs to be devoted to the appropriateness of various risk comparison procedures.

under the rules of evidence which apply to civil actions in the courts.

These analytic problems raise several legal and policy issues. It could be argued that use of sloppy comparisons to make decisions constitutes a denial of due process, in that persons who are likely to be adversely affected have little opportunity, in a regulatory proceeding on a particular risk, to challenge the estimates of other societal risks or regulatory determinations being used as comparisons. Sloppy, ad hoc comparisons also provide a basis for arguing on judicial review that an agency's ultimate decision is arbitrary or is not based on substantial evidence and is therefore invalid—despite the cases discussed earlier which were decided by courts under the pressure of extraordinary economic circumstances (shut down of a costly facility leading to huge economic losses for the facility owners). Repeated use of sloppy comparisons by an agency to decide in favor of polluting and other risk-creating activities could eventually lead to public and judicial recognition that legislated goals are being subverted, erode agency credibility and result in reversals of agency decisions. There is ample support for these dire predictions in the troubled history of agency uses of cost-benefit analysis and environmental impact analysis.

Agencies should carefully evaluate their proposed uses of comparative risk and the analytic and legal issues likely to arise, such as those discussed, and develop generic rules to provide for a principled framework which will govern their future uses of comparative risk methods and assure consistent and predictable practices.

The generic rule for an agency should provide criteria for assuring that only qualitatively comparable studies be relied on for the risk estimates to be compared, that the estimates deal with comparable populations at risk, and that the attributes of the risks being compared (e.g., economic impacts, pain and suffering, mortality and morbidity, etc.) be sufficiently similar to justify comparison.

The generic rule should also provide a set of evidentiary rules to govern the admissability and supporting documentation for the risk estimates, and procedures to assure that interested parties have the opportunity to evaluate and challenge the estimates being used for comparative purposes. Finally, the generic rule should include a policy statement and rationale for assuring that

future uses of comparative risk methods by the agency will be consistent with the goals set forth in the statute authorizing its particular regulatory program.[107]

Adopting an appropriate generic rule will not provide a complete solution, however. Comparative risk faces an analytic dilemma with possible policy consequences when the other risks being compared are those which have been determined to be de minimis, insignificant or otherwise unworthy of regulation by other agencies. Earlier discussion described the ad hoc and inconsistent approaches used by certain agencies such as EPA in establishing de minimis risk levels as limits for their regulatory actions. When a comparative risk approach is based on consideration of such risk limits, it clearly lacks convincing or consistent support.

Further, by relying on these de minimis risk limits set by other agencies under other statutes with their different provisions, an agency is vulnerable to the argument that its decisions are ultra vires and therefore invalid, in that they are based not on the provisions and criteria of its own statute, but on the criteria of the other statutes which governed the setting of risk limits by the other agencies.

Even if a standard or other regulatory decision is based on inter-industry comparisons of risk limits set by the same agency under the same statutory mandate, it may be found to be arbitrary under Judge Leventhal's rationale in *Portland Cement Association v. Ruckelshaus*,[108] or a deviation from statutory language, as in *Public Citizen v. Young*.[109]

Thus, an agency should use care in its choice of risk limits set by other agencies which it intends to use for comparison purposes. It must also establish that the outcome of its comparative risk exercise, its risk limit, is consistent with the criteria of its own enabling statute, irrespective of its consistency with the determination of other agencies.

107. The generic rule, suggested above, provides a process approach without recommending any particular risk limit outcome to permit agency flexibility in choosing the risk limit for each particular case. For an "outcome" approach proposing specific risk limits, *see* Cross, *supra* note 37, at 44-56. For example, Cross suggests that a lifetime mortality risk of one chance in one hundred thousand be set as the de minimis threshold of regulation for "average environmental risks." *Id.* at 51.

108. 486 F.2d 375 (D.C. Cir. 1973). *See supra* notes 100, 101 and accompanying text.

109. 831 F.2d 1108. *See supra* note 43.

VI. Evidentiary Use in Common Law Litigation

A. Background

Thousands of toxic tort actions now crowd the dockets of state and federal courts. The vast majority of these cases involve claims of personal injury from exposure to asbestos. Estimates of potential liability for the asbestos industry and their insurers range from $7.6 billion to $87.1 billion.

A new category of asbestos-related claims is now emerging which poses even greater liability potential. These claims allege injury to property caused by asbestos installed in buildings, particularly in schools. As a result:

> Thousands of school districts all over the country have sued asbestos product manufacturers, miners, and distributors, alleging damages caused by the presence of asbestos-containing materials in their school buildings. Claiming that the presence of asbestos in the buildings is a health hazard that must be remedied, the school districts seek indemnification for costs associated with inspection, removal, replacement, and encapsulation of asbestos-containing products, loss of the buildings' use during this process, and reduction in the buildings' market value. . . . Such claims . . . may even outdistance . . . bodily injury claims in dollar terms.[110]

The school district plaintiffs and others with similar property damage claims involving asbestos rely on the most favorable theories of tort and contract liability available to them. In general, the theories that are the most favorable are strict products liability and breach of warranty. The plaintiff can argue both in the same action but the formulation and availability of these theories varies from state to state.

Generally, in strict products liability:

> the plaintiff is not required to impugn the conduct of the maker or other seller. . . . [T]he product must be in 'a defective condition unreasonably dangerous.' This simply means that the product must be defective in the kind of way that subjects persons or tangible property to an unreasonable risk of harm.[111]

110. Arness & Eliason, *Insurance Coverage for Property Damage in Asbestos and Other Toxic Tort Cases*, 72 VA. L. REV. 943, 945 (1986) (footnote omitted). "About 15,000 school districts are participating in a class action against 55 defendants. . . . In addition, about 150 school districts are proceeding individually." *Id.* at 945 n.9.

111. PROSSER AND KEETON ON TORTS, *supra* note 6, § 99 at 695 (citing § 402A of the RESTATEMENT (SECOND) OF TORTS).

In breach of warranty actions, the plaintiff must prove that the asbestos product does not conform to the defendant's express or implied representations. Most plaintiffs in the asbestos cases rely on the more favorable implied warranty:

> Recovery under an implied warranty theory . . . does not rest on the written or spoken words of the seller. Rather, it rests on the implied warranty of merchantability, which the Uniform Commercial Code has codified. This implied warranty requires the manufacturer to produce goods that are of merchantable quality and that are reasonably fit for their intended purpose. To recover . . . the plaintiff must prove that . . . (4) the defective nature of the goods caused the injury both proximately and in fact . . . .[112]

Thus, under both theories, litigants in such property damage cases involving asbestos in buildings must address the issue of whether the asbestos product as presently situated in a particular building is defective, i.e., whether it poses an unreasonable health risk to exposed persons (e.g., school children, teachers, and other employees), thereby renders the structure unfit for continued use and consequently injures the property interest of the plaintiff.

In addressing this issue, both parties must deal with factual questions about prospective causation of harm to exposed persons, and this inevitably leads to expert testimony on health risk estimates. The expert views on health estimates may converge, but more likely will conflict. In either case, the ultimate question is then raised, namely, what level of health risk is unreasonable.

B. Expert Testimony

In several cases, defendants have sought to use comparative risk evidence to convince the jury that the asbestos products as installed, and the health risks as estimated, do not constitute an unreasonable risk to exposed persons and thereby do not make the structure unfit nor impair the plaintiff's property interest.

In *County of Anderson, Tennessee v. United States Gypsum Co.*,[113] defendants' expert witness, Dr. Kenny Crump, a biostatistician and consultant, testified under direct examination by defendant's attorney as to the nature and value of probabilistic risk assessments and then sought to explain the difference between his estimate of

112. *Special Project—An Analysis of the Legal, Social and Political Issues Raised by Asbestos Litigation*, 36 VAND. L. REV. 573, 585 (1983) (footnotes omitted).

113. Civ. Action No. 3-83-511 (E.D. Tenn. 1985).

.001 asbestos fibers per c.c. in the Anderson schools and 5.00 fibers per c.c., which he offered as the level "that can cause disease."

> Well, five fibers per cc is five thousand times larger than the .001 fibers per cc. A difference of five thousand is somewhat difficult to grasp. If you think of a tooth pick which is a little less than three inches long, it would take three football fields stretched end to end to be five thousand times as long as a toothpick. . . . [or] four Norris Dams stretched end to end to equal five thousand times the length of a toothpick.[114]
>
> . . . .
>
> If a person is exposed to .001 fibers per c.c., he would have to be exposed for 5,000 years in order to receive exposure equal to five fibers for one year.[115]

Crump then began his comparative risk testimony with a table of risk estimates:

> The first number here is the risk of cancer from smoking cigarettes for 20 years. Assume one pack per day . . . . The risk from smoking cigarettes I estimate to be 88,000 per million persons. That's a risk of almost one in ten. Now I personally consider that to be a high risk . . . .[116]

He then proceeded to discuss other risks in the table in descending order of magnitude: drinking diet soft drinks containing saccharin (170 per million), inhaling side-stream smoke (110 per million), drinking chlorinated water in Anderson County (26 to 17 per million), riding in a school bus (50 per million), eating peanut butter which contains the naturally-occurring carcinogen aflatoxin (11 per million), living in a brick house with radon gas (4 per million).[117] He then compared these numerical estimates with his estimates of .8 to .7 per million risk from attending the Anderson county junior and senior high schools and concluded that for the senior high school, "one would have to wait 4,000 years before you would expect to see a single cancer," and that for the junior high school, "you would expect to wait for 12,000 years . . . ."[118]

114. Transcript of Proceedings March 7, 1985 at 2467, County of Anderson, Tennessee v. United States Gypsum Co., Civ. Action No. 3-83-511 (E.D. Tenn. 1985).

115. *Id* at 2470.

116. *Id.* at 2475.

117. *Id.* at 2475-79.

118. *Id.* at 2479.

He then offered several variations on the comparative risk theme. These included a bar graph illustrating the relative magnitudes of the tabulated risks previously discussed:

> We have had to take smoking off the chart, we would have to make the chart a quarter of a mile long to include smoking. If you want to, imagine in your mind a line here [that] goes ten blocks or so away. . . . The longest one here is saccharin which is about . . . three feet long . . . two small bars here are the risk from being exposed . . . in these schools . . . .[119]

Crump also used a table showing his estimates of loss of life expectancy for each of the risks:

> If you smoke cigarettes for twenty years, that activity will cause you to lose between two and five years off of your life. . . . Drinking one diet soft drink . . . throughout your whole life . . . would reduce your life expectancy by 22 hours. . . . Drinking the water in Anderson County or Knoxville throughout your entire life [and life] expectancy would be reduced by two to three hours. . . .
>
> Using the exact same methods for asbestos risks and exposure to two schools for three years I estimate the loss of life expectancy . . . [for] Norwood Junior High . . . would be six minutes. . . . The loss . . . for attending Clinton Senior would be five minutes.[120]

Direct examination concluded with the following question and answer:

> Q: Dr. Crump, based on your professional experiences, do you have an opinion as to whether asbestos at the level to exist in the Anderson County schools created any unreasonable risk of harm to the employees or students?
>
> A: I have compared the risk and found them to be less than [the] risk of other activities we consider to be safe and my conclusion is there was not an unreasonable risk of harm from exposures in those schools.[121]

Plaintiff's attorney then cross-examined Crump on several key points to undermine his testimony. The initial line of questioning sought to get Crump to admit "that there is a statistical risk . . . of developing an asbestos related disease and dying from it . . . [as] depicted in that chart at Norwood . . . and Clinton."[122] Despite repeated denials, Crump finally admitted under continuing exam-

119. *Id.* at 2481.
120. *Id.* at 2482-83.
121. *Id.* at 2483-84.
122. *Id.* at 2485.

ination that his chart showed an "upper limit" for statistical risk for each activity including attending the two schools.[123] The next line of questioning brought Crump to disclose his extensive work as consultant and expert witness for numerous industrial organizations over several years, including the industrial Asbestos Information Association, Johns-Manville, W.R. Grace & Co. and other asbestos producers, and the fact that he had never consulted for a school board.[124] This was followed by cross-examining Crump on the uncertainties inherent in quantitative risk assessment. Plaintiffs' counsel elicited Crump's admission as to these uncertainties and acknowledgement of his pre-trial published statements to this effect.[125]

Cross-examination was then targeted on the quality of Crump's risk estimates for the two schools in question and secured admissions by Crump that he had not done such studies before; had not visited the two schools in question; had relied on air sampling data on the two schools to develop his risk estimates, but had not heard of various personal observations from persons at the school as to visibly heavier concentrations of fibers during air conditioning repairs and other special circumstances; had not considered the synergistic effects of smoking in an asbestos environment; had not considered employee exposure over a thirty year job period, but only student exposure over three years; and had not considered the cumulative risk for the same students attending both schools over a period of six years. These questions forced Crump to offer various revised estimates as to student risk, up from .7 and .8 per million to 1.5 per million for children attending both schools, and to 2 per million for student smokers attending one of the schools. Thus, plaintiff's attorney worked at impugning Crump's objectivity and expertise, the quality of his risk analysis and resultant estimates.[126]

Crump has offered similar risk estimates, comparisons and opinions about the reasonableness of asbestos risks in other cases as an expert for defendants and added risks from taking aspirin, having chest X-rays and inhaling radon gas in masonry school buildings to his repertoire of risk comparisons. He faced increasingly intensive cross-examinations in these cases. In some of

123. *Id.* at 2488.
124. *Id.* at 2488-96.
125. *Id.* at 2489-91.
126. *Id.* at 2496-509.

these cases, cross-examination has exposed important disparities between the methods used by Crump to develop the risk estimates used in his comparative risk tables and charts, such as his use of a *threshold* for asbestos risk (5 fibers per c.c.), in contrast to his use of a *linear dose-response* or *no threshold approach* for other risks being compared, a disparity of method which enlarges the difference between the asbestos risks and the other risks.[127]

At this time, one cannot fully evaluate how comparative risk evidence influences outcomes in these jury trials. Some cases have not been fully resolved or have been settled out of court. Many trial court decisions are not reported. Other considerations may influence outcomes (e.g., evidence of defendant's failure to warn or deliberate non-disclosure). Additionally some courts have excluded the comparative risk evidence offered by the defendants.

For example, *City of Greenville v. W.R. Grace & Co.*[128] marked the first verdict against a defendant in cases involving property damage from installed asbestos products. Grace was ordered to pay $6.4 million in actual damages and $2 million in punitive damages for its sale of asbestos fire-proofing materials to the city in 1971 without disclosing that the materials contained asbestos. In this case, district court excluded Grace's comparative risk evidence, under Federal Rule of Evidence 403, on the ground that the probative value of such evidence was substantially outweighed by the risk of jury confusion and undue delay.[129]

On appeal to the Court of Appeals for the Fourth Circuit, Grace contended that "the evidence presented at trial was insufficient to support a finding that the levels of asbestos contamination . . . posed a serious risk to the building's occupants,"[130] and that the district court had erred in refusing to admit its comparative risk evidence which included data on risks posed by peanut butter, diet soft drinks and other products.[131] In affirming the district court decision, the court of appeals noted that Greenville's experts had used techniques accepted in the scientific com-

127. *See* Trial Transcript at 1429, Spartanburg School District Seven v. National Gypsum Co., Civ. Action No. 83-1744-14 (D.S.C. July 29, 1985); Trial Transcript at 585, City of Greenville v. W.R. Grace & Co., 640 F. Supp. 559 (D.S.C. 1986) (No. 85-1693-3).

128. City of Greenville v. W.R. Grace & Co., 640 F. Supp. 559 (1986).

129. *Id.* at 571-72. *See also* Asbestos Litigation Reporter (Andrews Publications) at 11,735-36 (Feb. 21, 1986) and discussion in City of Greenville v. W.R. Grace & Co., 827 F.2d 975, 981 n.3 (4th Cir. 1987).

130. 827 F.2d at 980 n.2.

131. *Id.* at 981 n.3.

munity to estimate the risk, and that their testimony therefore "could reasonably support a jury finding that the levels of asbestos contamination . . . posed significant health risks."[132] Further, it noted that Grace's claim of district court error in excluding comparative risk evidence was without merit, as Grace's counsel had conceded during oral argument, and "the District Court acted within its discretion in excluding the 'comparative risk' evidence."[133]

Since *Greenville*, several other verdicts have been reached against defendants.[134] In one case in which Crump's comparative risk testimony was admitted and verdict returned for the defendant, a new trial has been ordered because of a faulty jury instruction.[135]

The admissability of comparative risk evidence in personal injury and property damage actions has long troubled the courts. The reasons were cogently stated in a recent decision of the Supreme Judicial Court of Massachusetts, *Kromhout v. Commonwealth of Massachusetts*.[136] In this case, plaintiff sought to establish that the state was liable in tort for the accidental death in 1981 of her husband, a motorist, due to a drainage defect in a state highway. During the trial, the plaintiff introduced evidence of twenty-one accidents at the same site, during the six years preceding her husband's accident, and plaintiff's expert on transportation testified that, in his opinion, this number of accidents at the same site in a six year period was significant. The state's expert testified that the total of twenty-one accidents was not significant. The jury returned a verdict for the plaintiff.

Following appeal to the Supreme Judicial Court by the state, the Court held that plaintiff's evidence was not admissible at trial, reversed the trial court judgment and remanded the case for a new trial. In finding the admission of such evidence to be reversible error, the Supreme Judicial Court provided the following rationale:

132. *Id.* at 980 n.2.

133. *Id.* at 981 n.3.

134. *See New Trial Ordered in S.C. Asbestos Case*, Nat'l L.J., December 15, 1986, at 3, col. 1.

135. Spartanburg County School District Seven v. National Gypsum Co., 805 F.2d 1148 (4th Cir. 1986). The jury was erroneously instructed that the state of the art was a defense to a breach of warranty action. The court did not address plaintiffs' allegation that defendants had concealed certain documents, as reported by the National Law Journal article, *supra* note 134.

136. 398 Mass. 687, 500 N.E.2d 789 (1986).

> "The admissability of evidence of injury to others at other times by reason of the same thing that caused the plaintiff's injury, for the purpose of showing that thing to be dangerous, has often come before this court. Such evidence is open to grave objections. Its persuasive force depends upon similarity in the circumstances of different injuries, of which it is hard to be certain. Substantial identity in the alleged defective condition is only the first essential. The person who was injured at the time to which the offered evidence relates may have been defective in eyesight, feeble, or careless. The fact that he was injured may have little or no bearing upon the danger to a normal traveller. Moreover, though the same defective condition may have been present at both times, the actual causes of the two injuries may have been different. Unless a comparison of the circumstances and causes of the two injuries is made, the injury to another is without significance. But if such a comparison is undertaken, the minds of the jurors must be diverted from the injury on trial into a detailed and possibly protracted inquiry as to injuries received by others at various times. Those injuries have only a collateral and often minor bearing upon the case. As to them the opposing party will often be ill prepared to present evidence. There is danger that a jury may disregard the real differences in the circumstances of the two incidents, and find upon mere superficial similarity that a dangerous condition existed. Similar considerations apply where evidence that other people, confronted at other times with the same alleged danger, suffered no injury is offered to prove the want of a dangerous condition."
>
> It is true that where substantial identity in the circumstances appears, and the danger of unfairness, confusion or undue expenditure of time in the trial of collateral issues seems small, the admission of such evidence has resided in the judge's sound discretion. That was clearly not the case here. No such identity of circumstances was shown . . . .[137]

Six months earlier, the same court had affirmed the state agency decision based on comparative risk evidence in *Town of Brookline v. Commissioner Department of Environmental Quality Engineering*,[138] discussed previously, demonstrating the judiciary's differ-

137. 398 Mass. at 693, 500 N.E.2d at 793 (*quoting* Robitaille v. Neteco Comm. Theatre of North Attleboro, 305 Mass. 265, 266-67, 25 N.E.2d 749-50 (1940)). *See* discussion of the admissability of evidence in negligence cases as to prior accidents at a particular site, provided that the conditions at the time of the earlier accidents (or lack of accidents) were "substantially the same" and there is a "showing of the relevant conditions . . . prevailing at the time of the earlier accidents . . . ." C. KRAMER & D. KRAMER, EVIDENCE IN NEGLIGENCE CASES 58-61 (8th ed. 1987).

138. 398 Mass. 404, 497 N.E.2d 9 (1986). *See supra* notes 85-97.

ential standards for private civil actions and for regulatory decisionmaking.

C. Rules of Evidence and Judicial Concerns

Rules of evidence govern the admissability of all evidence at trial, including expert testimony as to comparative risk and expert opinion as to the ultimate factual question before the jury, such as whether a product is unreasonably dangerous.

Traditionally, these rules have varied from state to state, but many states have recently adopted the Federal Rules of Evidence,[139] which apply in federal courts, leading to greater uniformity of rules among these states. Nevertheless, complete uniformity in application is unachievable, since rules of evidence provide that issues regarding the admissability of expert testimony and opinions are left to the discretion of the trial courts.[140] Such discretion, which is exercised on a case-by-case basis by different judges in different states, inevitably leads to variability in the treatment of expert testimony and opinions.[141]

In general, rules of evidence seek to guarantee that evidence by witnesses, expert or non-expert, will be "relevant" and "material" as to the issues and "competent" in the sense that the evidence is not barred by any specific exclusionary rules.[142] Comparative risk evidence, such as the Crump evidence in the school cases discussed earlier, would have run a considerable risk of exclusion under rules of evidence in effect in many states

139. FED. R. EVID., Pub. L. No. 93-595, 88 Stat. 1926 (1975), codified at 28 U.S.C. app. 678 (1982).

140. *See* FED. R. EVID. 104(a) (qualifications of witnesses and admissability of evidence shall be determined by the court), and state counterparts, ALASKA R. EVID. 104(a); ARIZ. REV. STAT. ANN., Rules of Evidence, Rule 104(a); ARK. STAT. ANN. § 28-1001, Uniform Rules of Evidence, Rule 104(2); COLO. R. EVID. 104(a); FLA. STAT. ANN. § 90.105; HAW. R. STAT. § 626-1, Rules of Evidence, Rule 104(a); IDAHO R. EVID. 104(a); IOWA R. EVID. 104(a); ME. R. EVID. 104(a); MICH. R. EVID. 104(a); MINN. R. EVID. 104(a); MISS. R. EVID. 104(a); MONT. CODE ANN. tit. 26, ch. 10, Rules of Evidence, Rule 104(a); NEB. REV. STAT. § 27-104(a); NEV. REV. STAT. § 47.060; N.H. R. EVID. 104(a); N.M. R. EVID. 104(a); N.C. R. EVID. 104(a); N.D. R. EVID. 104(a); OHIO R. EVID. 104(a); OKLA. STAT. ANN., tit. 12, § 2105; OR. EVID. CODE 104(a); S.D. CODIFIED LAWS ANN. § 19-9-7 to -11; TEX. R. EVID. 104(a); UTAH R. EVID. 104(a); VT. R. EVID. 104(a); WASH. R. EVID. 104(a); W. VA. R. EVID. 104(a); WIS. STAT. ANN. § 901.04(1); WYO. R. EVID. 104(a). *See also* P.R. R. Evid. 9.

141. In addition, states have re-drafted and amended the Federal Rules of Evidence during adoption, creating another source of variation among states. State adoptions and variable results are discussed in Wroth, *The Federal Rules of Evidence in the States: A Ten Year Perspective*, 30 VILL. L. REV. 1315 (1985).

142. *See* C. KRAMER & D. KRAMER, *supra* note 137, at 3, 17-30.

before their adoption of the more liberal Federal Rules. The Crump evidence as to various risks in society based on studies done by others would most likely have been excluded under rules barring "hearsay" evidence, hearsay being "what someone other than the witness said or did . . . what the witness heard X say, rather than that which is based on his personal knowledge of observation."[143]

Similarly, expert opinion as to the ultimate factual issue, for example, whether a product is unreasonably dangerous, would not have been admissible under the rules and common law in effect in many states before their adoption of the Federal Rules. Such expert opinion evidence would have been subject to exclusion on several grounds: it would confuse the jury, cause undue delay, or displace the jury's function of resolving the ultimate factual issue; it would be based on studies and technical reports not before the court and therefore would not be subject to critical review or cross-examination by the opposing party; it would permit an expert to speculate and subjectively rely on unaccepted or unproven experiments.[144]

However, in federal and state courts now following the new Federal Rules, expert opinions are more readily admissible. Rule 702 provides for judicial admissability of expert testimony when it is "helpful," i.e., "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." Rule 704 provides that "testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." Further, rule 703 provides that expert opinions are judicially admissible when based on facts which either are introduced as evidence, or are of a kind "reasonably relied on by experts in the same field." Thus expert opinions and inferences can now be admitted even if the underlying facts or data are not admitted or are not admissible as hearsay. These and

143. *Id.* at 25 (footnote omitted) (quoting FED. R. EVID. 801(c), 802).

144. Evidence law on expert opinions became particularly restrictive in courts following the rule of Frye v. United States, 293 F. 1013 (D.C. Cir. 1923). The *Frye* rule, set forth in a case involving the exclusion of the results of a lie detector case, provides that "[w]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle . . . 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." *Id.* at 1014. See discussion of this general acceptance test in Weinstein, *Improving Expert Testimony*, 20 U. RICH. L. REV. 473, 476 (1986).

other provisions of the new Federal Rules have led to a considerable liberalization of evidence law.[145]

But new problems have arisen, according to Judge Jack Weinstein:

> The Federal Rules of Evidence and their state counterparts have thus produced an enormous loosening up of the restrictions on the admission of expert testimony . . . . This relaxation was needed to give the trier of fact convenient access to the reliable technical knowledge that is available in our modern society. As might be expected, however, the modification of the old rules has led to new difficulties.
>
> An expert can be found to testify to the truth of almost any factual theory, no matter how frivolous, thus validating the case sufficiently to avoid summary judgment and force the matter to trial. At the trial itself an expert's testimony can be used to obfuscate what would otherwise be a simple case. . . . Juries and judges can be, and sometimes are, misled by the expert-for-hire.
>
> . . . .
>
> New discretionary controls . . . may be needed to curb the potential abuses that have appeared. . . . But how can discretion be bridled in a manner predictable and fair? How can the nonexperts control the experts?[146]

Introduction of comparative risk testimony and expert opinions on the reasonableness of risk, as in the asbestos in schools cases previously discussed, illustrate the validity of these judicial concerns. Weinstein and others have proposed various measures, some of which bear on the use of comparative risk evidence. Their proposals include greater judicial supervision of expert testimony before trial, including pre-trial provision of all underlying records from which data were collected to the opposing party,[147] pre-trial conferences for the opposing parties with the persons who compiled the "underlying records,"[148] pre-trial agreement on the database,[149] and the taking of depositions from non-testi-

145. *See e.g.*, FED. R. EVID. 803(6), (8) and (18) (exceptions to hearsay rule for business records, public records and learned treatises). *See also* Weinstein, *supra* note 144, at 481-82, for a discussion regarding new exceptions to the hearsay rule for learned treatises, business records and government reports, which reinforce the liberalizing influence of the Federal Rules.

146. Weinstein, *supra* note 144, at 481-82.

147. *See* PANEL ON STATISTICAL ASSESSMENTS AS EVIDENCE IN THE COURTS, THE EVOLVING ROLE OF STATISTICAL ASSESSMENTS AS EVIDENCE IN THE COURTS 360.

148. *Id.*

149. *Id.* at 351.

fying experts.[150] These pre-trial procedures available to the judiciary would "subject expert testimony to more informed scrutiny by the opposition's experts and lawyers.[151]

Other reforms, cited by Weinstein, include professional licensing of experts as qualified for testimony in certain fields with violations subject to disciplinary action and the development and application of new ethical standards for expert witnesses.[152] Standards now being considered by a National Academy of Sciences' Panel would pertain to the reliability of statistical techniques, the disclosure of methodologies used, and other "aspects that may raise ethical considerations," and a requirement "that statistical experts who consult or testify in litigation maintain the degree of professional autonomy required by independent scientific research."[153]

Finally, stronger judicial supervision may be needed. According to Weinstein, who has presided over the Agent Orange litigation, this may take various forms, ranging from changes in allocating the burden of proof to greater use of court-appointed expert witnesses as permitted by the new Federal Rules (Rule 706), to court-commissioned studies by government agencies or impartial experts.[154]

This need for judicial activism may extend to greater use of summary judgment "to prevent the enormous waste of resources caused by taking baseless or overwhelmingly strong cases to trial,"[155] as in cases where "examination of the basis of an expert's opinion reveals that it is supported by no reliable evidence at all. . . . In other cases, an expert's opinion is supported by *some* credible evidence, but . . . there is other, much more persuasive evidence available which undermines the expert's opinion and which the expert is ignoring."[156] True to his words, Weinstein has granted summary judgment and dismissed a complaint filed by an alleged victim of Agent Orange, because the plaintiff's medical expert relied on a causation hypothesis without any scien-

150. *Id.* at 241.

151. Weinstein, *supra* note 144, at 484.

152. *Id.* at 485-86.

153. *Id.* (discussing study of PANEL ON STATISTICAL ASSESSMENTS AS EVIDENCE IN THE COURTS, *supra* note 147).

154. *Id.* at 486-91.

155. *Id.* at 492.

156. *Id.* at 493.

tific support and excluded other potential causes without any factual basis.[157]

Thus, use of expert testimony about comparative risk and expert opinion as to unreasonable risk is now more readily permitted by new evidentiary rules, but early experience has already led to judicial concern and action over abuses, including its unreliability and misleading influences. Experts therefore face a sensitized and increasingly critical judiciary, despite new evidentiary rules, and this in itself may work to promote more responsible testimony and opinions pertaining to risk comparisons. But a more systemic reform is needed to guide case-by-case decisions by the judiciary. Principles of responsibility and reliability in the use of comparative risk evidence should be developed by the scientific community to meet this need.[158]

VII. Conclusions

Now that risk analysts produce quantitative estimates of risk and these estimates can be statistically compared, many have proposed, and some have used, risk comparisons to resolve three risk decisionmaking problems: prioritizing risks to allocate regulatory resources, determining the risk limit in licensing and standard-setting actions and the common law or toxic tort problem of determining whether a risk at issue is unreasonable.

Use of risk comparisons for setting regulatory priorities has raised several issues that have yet to be resolved and that therefore obstruct full reliance on this approach. Some of the issues are legal in that several statutes that mandate risk regulation provide for it in a manner that militates against agency use of comparisons for setting priorities. But most of the issues pertain to the uncertainty of the risk estimates being compared and, more fundamentally, to their lack of comparability due to the absence

157. *See* In re Agent Orange Product Liability Litigation (Lilley), 611 F. Supp. 1267, 1280-83 (E.D.N.Y. 1985).

158. For recent general background as to evidentiary law relevant to experts and comparative risk testimony, *see* Weinstein, *supra* note 144; Wroth, *supra* note 141; C. Kramer & D. Kramer, *supra* note 137; Panel on Statistical Assessments as Evidence in the Courts, *supra* note 147. *See also* Carlson, *Policing the Bases of Modern Expert Testimony*, 39 Vand. L. Rev. 587 (1986); Reisel, *Discovery and Examination of Scientific Experts*, 32 Prac. Law. 59 (September 1986); Field & Baram, *Screening and Monitoring Data as Evidence in Legal Proceedings*, 28 J. Occupational Med. 946 (1986); Durst, *Evidentiary Use of OSHA Regulations*, 17 Trial Law. Q., No. 3, at 5 (1986); Faulk, *Strategic and Scientific Considerations in Toxic Tort Defense*, 26 S. Tex. L.J. 513 (1985).

of any accepted generic criteria for valuing the disparate types of risks in order to rank order them on a common scale. Nevertheless, some agencies have proceeded to use risk comparisons as one of several methods for structuring their regulatory priorities, particularly when the types of risks involved are essentially comparable, as in the case of the risk of death due to cancer.

Agency use of risk comparisons for setting the risk limits in their licensing and standard-setting decision processes is now occurring on an ad hoc basis, although the Nuclear Regulatory Commission has recently proposed to formally adopt a generic approach.[159] Several federal and state agency decisions in license cases based on risk comparisons have been affirmed in the courts as being reasonable and rational, despite revelations that such comparisons used risk estimates derived from studies of variable quality and studies which used different assumptions and analytic methods.[160]

Nevertheless, future judicial review may not so readily defer to agency expertise in making decisions on the basis of such ad hoc comparisons. Many of these comparisons have obviously been flawed in several material respects: for example, the lack of comparability of the risks, or of the exposed populations studied, and the ad hoc or opportunistic use of available risk estimates without a properly structured set of generic principles to guide agency use of risk comparisons. Appropriate generic rules could be developed by the agencies to avoid these problems and to assure that any use of comparative risk methods will be consistent with statutory mandates.

Finally, comparative risk evidence is also being used in toxic tort and related common law litigation on unreasonable risk issues, most prominently in the asbestos in schools cases. Expert testimony and opinions, based on risk comparisons, have been subject to extensive cross-examination, revealing various inadequacies including the expert's use of risk estimates derived from studies of variable quality, studies which use differing assumptions and analytic methods. The effectiveness of such testimony is an open question at this time. What is clear is that new, liberal rules of evidence used in federal and many state courts now per-

159. *See supra* notes 66-75 and accompanying text.
160. *See supra* notes 76-97 and accompanying text.

mit such testimony, a sharp departure from earlier rules restricting hearsay testimony and opinions in these courts.

But growing judicial dissatisfaction with the use of experts on risk is leading to the development of new means for curbing abuses in the use of expert testimony under the new rules of evidence. Some of these means involve greater judicial activism before trial and during trial, such as the summary dismissal of an action when a plaintiff's expert opinion has not been supported by reliable scientific evidence.[161] Other reforms are being developed within the scientific community and could provide a consistent set of principles for judicial use in determining the admissability of expert testimony and opinions, as well as for use by experts themselves to guarantee the quality of their testimony.

Thus, future use of comparative risk to set priorities and risk limits in the agencies, and to determine whether a risk is unreasonable in common law litigation, will depend to a considerable extent on the responsibility of its proponents. As agencies and courts grapple with the need to develop procedures for assuring the appropriate use of scientific expertise and risk comparisons, there is a concomitant need for the risk analysis community to deal with the substantive issues and put its own house in order. To do this, risk analysts must work to assure that professional attributes of objectivity and reliability, and humanistic considerations about the appropriateness of comparisons in particular circumstances, govern the use of comparative risk methods in the agencies and courts.

161. *See supra* notes 146-157 and accompanying text.