AMERICAN BAR ASSOCIATION
SECTION OF ADMINISTRATIVE LAW AND REGULATORY PRACTICE

RECOMMENDATION

RESOLVED, That the American Bar Association recommends that:

Any formal requirement, promulgated by the Congress (in legislation), the President (in executive orders), or an agency head (in directives or rules), that agencies of the Federal Government undertake formal risk assessments in advance of regulatory action concerning health and safety issues should be consistent with the following principles:

1. Risk assessment should provide scientific estimates and characterizations of the nature and magnitude of risks posed to human health, human safety and the integrity and quality of the environment, and should be based on careful analysis of the weight of all available evidence. The process should be constructed to avoid bias and political pressure. Where relevant, additional economic, social, and political factors that were not incorporated into the risk assessment should also be considered when risk managers make regulatory decisions.

2. Risk assessment requirements must allow for flexibility in assessing the variety of relevant risks and should acknowledge that risk assessors may exercise professional judgment on these matters.

3. Risk assessors should identify and explain their judgments, and an agency should document in the administrative record both its own evaluation of a risk assessment, and whether and how it was used in its decision process.

4. Peer review – though adding time and expense – can improve risk assessments. The nature, significance, and complexity of the risk assessment should dictate when peer review is used and the scope and nature of any peer review.

5. Risk assessments should explicitly acknowledge and explain the limitations of the process in terms of methodology, data, assumptions, uncertainty, and variability. In particular, agencies should fully disclose qualitative aspects of risk, the reasonable range of uncertainties, and the existence of variability in the populations exposed to the risk.

6. Risk comparisons can be helpful for placing risks in context, but risk assessments should be approached with care, particularly among dissimilar risks, and critical features of the compared risks should be fully disclosed.

7. Public procedures associated with risk assessment should be conducted through a transparent process that allows input from and understanding of the results by persons and groups interested. Particular efforts, proportional to the overall effort involved, should be made to reach persons and groups who do not have the technical expertise to use such materials easily.

8. Risk assessments can be useful across a broad range of agency programs and decisions. Risk assessments should be statutorily required, however, only for regulatory decisions of sufficient significance to warrant the effort. The amount of effort that goes into a risk assessment should be reasonable in relation to the significance and complexity of the decision, the value of additional information, and the need for expedition.

9. Any judicial review of a risk assessment should occur only as part of the review of a final agency action for which the assessment was made.

AMERICAN BAR ASSOCIATION
SECTION OF ADMINISTRATIVE LAW AND REGULATORY PRACTICE

REPORT

The accompanying resolution provides an opportunity for the American Bar Association to take a position on an important and timely issue of federal administrative law and regulatory practice: the role of risk assessment in agency decision-making. Congress has considered several bills incorporating risk assessment provisions across a wide range of environmental, safety, and health regulation.[1] None of the bills has yet passed both houses – though risk provisions have been included in other legislation[2] – so the ABA has the opportunity to help shape the present debate, as it has in previous recommendations concerning benefit-cost analysis. The legislation under serious consideration would require agencies to make more extensive use of risk assessment[3] and to follow certain guidelines in conducting risk assessments; it does not seek to replace the substantive standards contained in the numerous statutes to which the risk assessment requirement would apply. Accordingly, these recommendations do not address substantive regulatory standards.

Risk Assessment and Management

As its name suggests, risk assessment is a process for characterizing the probability and magnitude of certain adverse effects. The nature of these effects varies widely. The methods for assessing hazards for which the mechanisms of cause and effect are observable and relatively easy to measure are not particularly controversial. For other kinds of risks, the mechanism is less well understood and only probabilistic statements can be made about their fruition; these latter types of risk, in general, are the object of reform legislation.[4] For them, risk assessment is used to identify activities that require regulatory attention, to select the nature and stringency of an appropriate regulatory response, and to choose among the many potential objects of regulators' efforts. An overall purpose is to "organize and express what can be stated about risks that are not

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[1] *See, e.g.,* S. 981, 105th Cong., 1st Sess. (1997) (as amended by S. Amdt. No. 1644 (Feb. 4, 1998)); S. 2161, 105th Cong., 2d Sess. (1998); S. 343, 104th Cong., 1st Sess. (1995); H.R. 9, 104th Cong., 1st Sess. (1995); H.R. 1022, 104th Cong., 1st Sess. (1995). Some of the foregoing bills included cost-benefit analysis requirements, as well.

[2] *See, e.g.,* 21 U.S.C. § 300g-1(b)(3) (amended Safe Drinking Water Act).

[3] The change in this respect would be making risk assessments mandatory in a wide range of settings. Federal risk regulators already use risk assessment a great deal, on their own, in response to Executive Order 12,866, and to fulfill some statutory requirements.

[4] The legislation cited above does not clearly distinguish risk type, however. Consequently, as the recommendation and report discuss, it is important not to impose analytical techniques that are ill-suited to the hazard under consideration.

subject to direct observation and measurement"[5] – for chemicals having these characteristics, for example, based on an analysis of data concerning toxicity and exposure. Carcinogenicity, widely considered by regulatory agencies as the most sensitive measure of health and environmental harm, is a paradigmatic example of such a risk. Dissatisfaction with risk assessment methods tends to focus on probabilistic risk assessment, and many legislative proposals have been constructed from concepts that are most applicable to probabilistic risk. For these reasons, and not because the proposals are by their terms limited to such risks (see note 4), the recommendation concentrates on issues relating to probabilistic risk. As the recommendation and report emphasize, however, it is important that risk legislation be tailored to the kinds of hazards to which it applies.

The basic methodology for assessing these more probabilistic risks was set out in a 1983 report of the National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process* (known as the Red Book). The Red Book approach is the foundation of what might be called the state of the art of risk assessment, reflected in the most recent of the National Academy of Sciences reports on risk assessment, *Science and Judgment in Risk Assessment* (1994) and *Understanding Risk* (1996), and in the report of the Presidential/Congressional Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making* (1997). The Red book model of quantitative risk assessment has four distinct steps (a schematic depiction is attached as Figure 1):

- First, *hazard identification* determines whether a substance poses a hazard at all, without measuring in detail its potency or likely effects.
- Second, *dose-response* modeling predicts from testing data the toxic effect of a given amount of exposure to a given agent. This is the phase that uses the familiar (and often maligned) large-scale animal bioassays to reach estimates of toxic potency. To predict dose-response at low levels over long periods, however, the risk assessor must usually extrapolate from experimental data. The choices among extrapolation models are often controversial because the biological mechanisms of toxicity are poorly understood.
- The third step, *exposure assessment*, undertakes to estimate the amount of the agent with which humans or elements of the environment are likely to come in contact. A risk assessor is often confronted with many pathways between the hazardous substance and the human or ecological receptor, and extrapolating from exposure to actual dose involves more modeling of human and animal metabolism. The differing routes of exposure (ingestion, inhalation, or absorption) and metabolism yield an additional layer of complexity. Both the pathways and the routes of exposure are subject to considerable variation among individuals and among subpopulations. In addition, to assess the effects of regulatory action, the risk assessor must often predict future physical conditions and human behaviors.
- Fourth, *risk characterization* is the process of combining hazard and exposure data to calculate and communicate the risk. In the classic version, this is a quantitative exercise:

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[5] Joseph V. Rodricks *et al., Significant Risk Decisions in Federal Regulatory Agencies*, 7 REGULATORY TOXICOLOGY & PHARMACOLOGY 307, 307 (1987).

numerical values are attached to dose-response and exposure, they are multiplied, and a risk figure – usually, though not necessarily, expressed as an individual risk (for example, 1 in 1,000,000 or 1×10^{-6}) – is generated. The result is a quantitative evaluation that represents the excess deaths or illnesses expected from exposure to the toxic substances. The expression of the range of possible values, due to uncertainty and variability, is a continuing challenge for risk characterization. Risk characterization is also the appropriate location for describing relevant qualitative characteristics of risk,[6] including the nature of the effect (*e.g.*, open/covert, mechanical/toxic), the circumstances of its occurrence (*e.g.*, voluntary/involuntary, occupational, controlled by self/others), the identity of the risk receptors (*e.g.*, specific group/general population, vulnerability), and the potential consequences (*e.g.*, immediate/delayed, catastrophic).

The four steps described above comprise risk *assessment*. The Red Book distinguished this from risk *management*, the substantive decision to take or withhold regulatory action. The latter, unlike risk assessment, explicitly involves political, social, and economic policy questions, such as the acceptable level of risk and the appropriate regulatory response. Complete separation of assessment and management is impossible, however. Risk managers need to understand the limitations of risk assessment and risk assessors need to understand the informational needs of risk managers. Operating under conditions of profound uncertainty, incomplete data, and genuine differences between scientists in interpretation of and inferences from the available data, risk assessors inevitably make judgments about assumptions and estimates, judgments necessarily affected by policy. A clean distinction between assessment and management in not achievable; assessors and managers not only must understand each other, but inevitably they *affect* each other. Thus, a recent NAS study of risk assessment suggested that the distinction between risk assessment and management could be taken too literally:

> A more subtle and less widely recognized impediment to good decisionmaking on risk arises from a rigid adherence to the principle of separating risk assessment from risk management. The call to keep these two functions distinct was originally articulated in response to a widespread perception that EPA was making judgments on the risk posed by a particular substance not on the basis of science, but rather on the basis of its willingness to regulate the substance. The purpose of separation, however, was not to prevent any exercise of policy judgment at all when evaluating science or to prevent risk managers from influencing the type of information that assessors would collect, analyze, or present. Indeed, the Red Book made it clear that judgment (also referred to as risk-assessment policy or science policy) would be required even during the phase of risk assessment. The present committee concludes further that the science-policy judgments that EPA makes in the course of risk assessment would be improved if they were more clearly informed by the agency's priorities and goals in risk management. Protecting the integrity of the risk assessment, while

[6]NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 155-66 (1996); 2 PRESIDENTIAL/CONGRESSIONAL COMMISSION ON RISK ASSESSMENT AND MANAGEMENT, RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION-MAKING 86 (1997).

> building more productive linkages to make risk assessment more accurate and relevant to risk management, will be essential as the agency proceeds to regulate the residual risks of hazardous air pollutants.[7]

Nevertheless, as the NAS recognized, the distinction is a useful guide for many purposes, most importantly for clearly disclosing the location of policy judgments throughout the assessment-management process.

Uncertainty and Its Remedies

The fundamental challenge to toxics regulation under the Red Book model is uncertainty in the mechanism of disease and lack of adequate data. The conclusion reached in the 1984 NAS report, *Toxicity Testing* – "the information available . . . is scanty, and the resources . . . do not suffice to test all chemicals for every possible health effect"[8] – remains largely accurate and applies to virtually all areas of toxic risk regulation.[9] As an analytical tool, risk assessment both responds to and is limited by this uncertainty. It is a framework for using existing data, yet it accepts "placeholders" – assumptions or estimates – where such data are not available.

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[7]NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 259-60 (1994).

[8]NATIONAL ACADEMY OF SCIENCES, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES 205-208 (1984). The 1983 Red Book anticipated this issue in its discussion of the need for "inference guidelines." RED BOOK, *supra*, at 51-85.

[9]*See, e.g.,* JOHN WARGO, OUR CHILDREN'S TOXIC LEGACY 270-76 (2d ed. 1998); SCIENCE AND JUDGMENT, *supra*, at 144-59 (hazardous air pollutants); OFFICE OF TECHNOLOGY ASSESSMENT, COMPLEX CLEANUP: THE ENVIRONMENTAL LEGACY OF NUCLEAR WEAPONS PRODUCTION 62-64 (1991); CARL F. CRANOR, REGULATING TOXIC SUBSTANCES: A PHILOSOPHY OF SCIENCE AND THE LAW 4 (1993) (summarizing studies by the Office of Technology Assessment in 1982 and 1987); John Chelen, Erasing the Data Deficit, 15 THE ENVTL. FORUM (ENVTL. L. INST.) 35 (Jan./Feb. 1998); Wendy Wagner, *Choosing Ignorance in the Manufacturing of Toxic Products*, 82 CORN. L. REV. 733 (1997); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 284-98 (1991); Sidney A. Shapiro & Thomas O. McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 YALE J. ON REG. 1, 5 (1989); Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1796-99 (1989). One recent survey of chemicals found "sufficient information for safety assessment" for 7% of TRI chemicals released to air, 34% of chemicals released to water, and 3% of all high-volume chemicals. David Roe & William S. Pease, *Toxic Ignorance*, THE ENVTL. FORUM, May/June 1998, at 26-27. In its study of carcinogens in the human diet, the NAS concluded:

> Numerous and extensive gaps in the current knowledge base were apparent as the committee endeavored to examine the risk of human cancer from naturally occurring versus synthetic components of the diet. These gaps are so large – and resources are so limited– that careful prioritization of further research efforts is essential. The following recommendations emphasize the need for expanded epidemiologic studies, more human exposure data, improved and enhanced testing methods, more detailed data on dietary components, and further mechanistic studies, if these gaps are to be filled. These research endeavors may prove inadequate, however, when the complexity and variability of diets and food composition, as well as human behavior, are considered.

NATIONAL RESEARCH COUNCIL, CARCINOGENS AND ANTICARCINOGENS IN THE HUMAN DIET 11-12 (1996).

On the question of toxic potency, it is typical, at least in the absence of conclusive evidence to the contrary, to assume that a carcinogen has no "threshold" concentration below which it poses no risk of causing cancer. Since existing understandings of the mechanism of the disease do not clearly demonstrate a threshold at very low doses, the conservative or precautionary approach is to assume that there is none.[10] Likewise, in calculating dose, assumptions must be made about the conversion factor for translating the results of animal testing to humans and about the dose-response model to be used.[11] These kinds of assumptions are science-based in the sense that there is empirical or theoretical basis for them and that there is not a clear demonstration to the contrary, but also reflect a policy choice to adopt, in the face of uncertainty, a conservative measure of risk. For exposure assessment, the more typical unknowns are not so much uncertainty as variability. Rates of exposure and metabolism, for example, may differ significantly among individuals and populations. Again, the standard practice is to choose the conservative or precautionary assumption, that is, to choose the value that lies at the high end of the spectrum of exposure or metabolism. It is common for risk assessments to rely upon a hypothetical "maximally exposed individual," whose characteristics are designed to assure that almost no one in the real world would be more exposed (though it does not always work out that way[12]).

The conservative assumptions regarding toxicity and exposure are often combined in a given risk assessment. This use of multiple conservatism reflects a highly contested policy choice in risk assessment to calculate and present only "upper bound" or "worst case" risk estimates to vindicate the protective purposes of environmental, safety, and health legislation.

There are alternatives to providing only upper bound estimates, and these alternatives are prominent features of proposed risk legislation. One would be to present "best estimates" as part of a full distribution; another, to invoke "best science" in making assumptions. But the lack of information may be so profound that choosing a "best" value is little more than a guess or a hunch. Simply choosing an average is little better; where variability is great, a single figure can be highly misleading. Another response is to abandon the practice of using point estimates in risk assessments in favor of ranges of estimates that convey the upper and lower bounds within which the actual value likely lies.[13] Full disclosure of knowns and unknowns in the assessment,

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[10]Conservatism is not limited to risk analysis, of course. Economic analyses of regulations frequently use highly conservative assumptions. *See, e.g.,* Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981, 2042-56 (1998) (describing assumptions behind discount rates).

[11]For one chemical, the differences between the dose-response models were memorably described as "not knowing whether one has enough money to buy a cup of coffee or pay off the national debt." Richard Cothern *et al., Estimating Risk to Human Health*, 20 ENVTL. SCI. & TECH. 111, 115 (1986).

[12]*See* Adam M. Finkel, *Is Risk Assessment Really Too Conservative?: Revising in the Revisionists*, 14 COLUM. J. ENVTL. L. 427 (1987).

[13] A refinement of risk ranges seeks to assign probabilities to each part of the range through a statistical technique called Monte Carlo analysis, in which the known variation in the various components of the risk calculation are combined repeatedly in random combinations to get a sense of the most likely final values. *See* Susan Poulter, *Monte Carlo Simulations in Risk Assessment–Science, Policy & Legal Issues,* 9 RISK: HEALTH, SAFETY & ENV'T 7 (1998).

so that the nature and extent of the conservatism can be taken into account by the risk manager, can be used in conjunction with any of these substantive techniques.[14] This approach is fully consistent with the view that risk assessment is a tool to make a fully informed policy decision.

The Controversy

There are, very roughly speaking, three schools of thought on the proper role of risk assessment in regulatory decisionmaking. Strong proponents of risk assessment and full use of scientific information assert that risk assessment can be a scientifically objective, unbiased process. For them, a risk assessment with complex factual or theoretical bases should provide a multidimensional profile of risk, which may include conservative estimates; but it must include the most scientifically plausible estimates in the professional judgement of the risk assessor. To be sure, where data is missing or of poor quality risk assessors must be able to fill gaps with assumptions based on scientific professional judgement. Risk *managers*, who decide regulatory issues on the basis of the full information available to them, must be able to consider other relevant information, such as economic, social and political factors extrinsic to the assessment. But these proponents believe that the present "worst-case" only approach in certain agencies biases regulatory decisionmaking in favor of unnecessarily prescriptive regulations and distorts the allocation of resources among risk reduction priorities.

Risk assessment skeptics criticize risk assessment as an incomplete expression of the nature and extent of the environmental hazards that environmental, health, and safety legislation addresses, because unquantifiable aspects of risk are equally or more important than quantified expressions of the risk of death from cancer. Uncertainty concerning physiological mechanisms of cancer (and some other effects) and inadequacies in the data measuring extent of effects is profound and fatally undermines the validity of its conclusions. Moreover, the characterization of environmental, health, and safety hazards as a technical calculation systematically advantages those with access to technical expertise and tends to exclude those who do not.

The middle-ground, or pragmatic, position recognizes both the utility and limitations of risk assessment. Risk assessment is a valuable addition to the larger suite of information that regulators consider; however, it is a developing methodology and the needed data are often missing or of poor quality. Under these circumstances, risk assessors must be able to fill gaps with assumptions, but should replace the assumptions as better data become available. To the extent that the use of particular assumptions or the remaining uncertainty are problematic, all agree that the best cure is *transparency*, that is, full disclosure in the process, explanation of choices, and appropriate participation by affected parties. The National Academy of Sciences and the Presidential/Congressional Commission adopt pragmatic positions.

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[14] *See, e.g.,* Contra Costa County v. Pena, 1998 WL 164966, *7-*8 (N.D. Cal. 1998) (approving agency's decision not to follow "upper bound" risk values); Sierra Club v. Utah Solid and Hazardous Waste Control Board, 964 P.2d 335, 341-44 (Utah App. 1998) (approving agency's discounting of explicitly "overstated" risk assessment results); John S. Applegate, *A Beginning and Not an End in Itself: The Role of Risk Assessment in Environmental Decisionmaking*, 63 U. CIN. L. REV. 1643, 1653-55 (1995) (describing the role of conservative estimates in reaching a middle-ground level of clean-up at a Superfund site).

The Recommendations

> *Risk assessment, a process for characterizing the probability and magnitude of some adverse effects of potentially regulated conduct, can be used to identify activities that require regulatory attention, to select the nature and stringency of an appropriate regulatory response, and to choose among the many potential objects of regulators' efforts. It is thus a valuable tool for improving regulatory decisionmaking relating to health, safety, and environmental protection, which agencies should ordinarily use in connection with significant regulatory actions on such matters. Any formal requirement, promulgated by the Congress (in legislation), the President (in executive orders), or an agency head (in directives or rules), that agencies of the Federal Government undertake formal risk assessments in advance of regulatory action concerning health and safety issues should be consistent with the following principles:*

The recommendation favors agency use of risk assessment for significant regulatory actions, but does not take a position on the question whether Congress should require it – either generally or on a statute-by-statute basis. Assuming that such proposals will be made, it describes the appropriate characteristics of such legislation, should Congress enact it. The preamble clearly recognizes, however, the value of risk assessment to the regulatory process and attempts to convey both its strengths and its limitations.

> *1. Risk assessment considers an important and useful subset of information relevant to regulatory decisions. It should provide scientific estimates and characterizations of the nature and magnitude of risks posed to human health, human safety and the integrity and quality of the environment, and should be based on careful analysis of the weight of all available evidence. The process should be constructed to avoid bias and political pressure. Other relevant information, such as economic, social and political factors that do not relate to risk assessment may also be important to a risk manager and, if so, should be considered by him or her.*

Paragraph 1 locates risk assessment in the regulatory process and distinguishes between risk assessment and management. It also notes that the information presented in a risk assessment is not the only information relevant to agency decisionmakers. The latter is determined primarily by the applicable substantive statute.

One of the key debates in drafting this recommendation was the extent to which risk assessment should be characterized as "objective." Those most strongly viewing it in this way would prefer that it include statements that risk assessment should be an objective process and should neither minimize nor exaggerate the nature and magnitude of risks. Perhaps the heart of their concern is to work against an assessment process that is politicized or biased. Those more skeptical of the process, on the other hand, are concerned that repeated and focused attention to "objectivity" will tend to obscure that risk assessments will often involve judgment (a point on which all agree), and encourage the mischaracterization of the results of risk assessment as unqualified "truth." The compromise language stresses that risk assessment deals with

"scientific estimates and characterizations" about risk, that are based on "careful analysis of all available evidence." This should be taken to refer to a recognized risk assessment method and to indicate that the methods to be used are analytical and not merely political or rhetorical. However, "scientific" should not be read to limit risk assessment to quantitative (numerical) techniques or results. Qualitative (narrative) techniques and results can be appropriate in some situations, for example, in priority setting, discussed below.

A more detailed statement of rationale, used in earlier drafts and reflective of both the tensions and the aspirations involved in risk assessment, is as follows:

> Risk assessment considers an important and useful if not comprehensive set of information relevant to regulatory decisions. It should provide scientific assessments, estimates and characterizations of the nature and magnitude of risks to human health, human safety and the environment, based on a careful analysis of the weight and quality of scientific evidence, including such site-specific and substance-specific information as may be available, as well as information about the range and likely distribution of risk. Its purpose is to gather, analyze, organize, and present relevant information, in order to help risk managers and the public understand risk. To be avoided is a process that is politicized or biased. Scientific findings and professional judgments embodied in risk assessments should be explicitly distinguished from risk management. It is important to recognize that other relevant information, such as economic, social and political factors extrinsic to the assessment may also be important to and considered by risk managers, who decide regulatory issues on the basis of the full information available to them.
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> *2. Risk assessment requirements must allow for flexibility in assessing the variety of relevant risks – safety as well as health or environmental risks, acute risks as well as chronic ones – and for developments in expertise, methodology, and scientific knowledge, and should acknowledge that risk assessors may exercise professional judgment on these matters.*

Paragraph 2 emphasizes the need for flexibility in specifying risk assessment methods to account for developments in the field and for the many types of hazards to which the proposed legislation would apply. As to the first point, risk assessment is a relatively new area of intensive interest, and the state of the art is in constant flux. As to the latter, it was previously noted that the Red Book model (on which many risk bills appear to rely) is inapplicable to many environmental, health, and safety hazards, in particular deterministic ones. (Dose-response analysis, for example, means nothing in the context of automobile accidents.) Unavoidably, many judgments go into assessing a risk. This is in some part due to the uncertainties described above, but it is also due to methodological choices that will always be needed. Thus, the exact components of a risk assessment cannot be mandated in advance. The choice of analytical method appropriate to assess a specific type of risk should therefore remain with the relevant agency. We must rely to a large extent on the professional judgment of risk assessors, as the recommendation recognizes.

3. To promote transparency in risk assessment, risk assessors should identify and explain their judgments, and an agency should document in the administrative record both its own evaluation of a risk assessment, and whether and how it was used in its decision process.

Since the content of these judgments is a matter of concern and advance prescription is infeasible, the recommendation adopts the requirement that judgmental options be identified and explained. Here, as elsewhere in the recommendations, transparency (*i.e.*, disclosure, explanation, and appropriate public participation) is a cornerstone virtually all commentators on risk assessment recognize. This is also the resolution adopted by the major NAS and Presidential/Congressional Commission reports.

Risk assessments should specify the limitations of the available data, the assumptions and extrapolations employed, the uncertainties involved, and the risk assessor's view of whether in the particular matter at issue based on the weight of the evidence and other factors the uncertainties are substantial enough to undermine the methodology's scientific validity. The administrative agency should evaluate the scientific validity of the methodology and specify in the administrative record the weight, if any, given to the risk assessment in the risk management process. It should explain in the administrative record an difference it has with regard to the nature, frequency, magnitude or distribution of the risk as found by the risk assessors. When making a risk management decision, of course, an administrative agency will often consider factors in addition to the results of the risk assessment.

4. Peer review of risk assessments may be desirable for the purposes of improving their quality, transparency, and credibility in the presence of complex factual or theoretical issues, although its potential for adding expense and delay makes it inappropriate as a general requirement. The fact, scope and nature of peer review should be commensurate with the nature, significance, and complexity of the risk assessment.

Extensive peer review is strongly urged by proponents of risk assessment as a way to assure that the judgments discussed above are reasonable. Peer review also emphasizes the scientific nature of the analytical process. Skeptics, on the other hand, are concerned that routine peer review would unnecessarily weigh down an already lengthy and expensive process. In their view, transparency and public participation give ample opportunities for challenges to the risk assessors' judgments. They also believe that risk analyses should not be subjected to peer review standards that are not applied to equally judgmental economic analyses.[15] The recommendation takes the position that there is merit in both views. Accordingly, peer review is recommended, but limited to situations in which it is most likely to improve the analysis, such as complex or novel problems, or add authority, such as highly controversial situations.

[15]The Presidential/Congressional Commission on Risk Assessment also observed, "Peer review of economic and social science information should have as high a priority as peer review of health, ecologic, and engineering information." 2 PRESIDENTIAL/CONGRESSIONAL COMM'N, *supra*, at 103.

Consistent with the rest of the recommendation, paragraph 4 counsels flexibility in the extent and form of peer review. When peer review is needed, its scope should be tailored to the issues that require review, and the extent of the effort should be proportionate to the size and complexity of the risk assessment and the relevant issues. Peer review typically means that, prior to publication, the agency sends a draft of the risk assessment to a group of reviewers for scientific review and comment, and then makes appropriate revisions or responses. Agencies can accomplish the same result in different ways – for example, OSHA's hearing procedure for proposed standards permits a detailed exchange among risk assessors from the agency, industry, labor, and other interested parties.

A second major issue is the independence of the peer reviewers. Certainly, peer reviewers in the same office as the assessors have too little distance from the authors. On the other hand, depending on the circumstances, peer reviewers in other government agencies or even in other parts of the same agency[16] may well have sufficient independence. To require hiring private consultants in all cases would be very expensive and raise potential conflicts of interest with other clients. The recommendation is silent on the identity of peer reviewers, but it is to be understood that expertise and independence in fact are the key qualifications. It would be preferable, where feasible, to identify reviewers who have neither employment nor consultancy relations with the agency, industries, or citizen groups concerned.

> *5. Risk assessments must explicitly acknowledge and explain the limitations of the process in terms of methodology, data, assumptions, uncertainty, and variability. In particular, agencies should fully disclose qualitative aspects of risk, the reasonable range of uncertainties, and the existence of variability in the populations exposed to the risk.*

The management of uncertainty and variability – through the use of assumptions, for example – is one of the most controversial areas of risk assessment. As previously noted, the recommendation relies primarily on transparency to reach a consensus view. Transparency has many independent virtues, as well. It places all of the contestable issues in the risk assessment on the table, so to speak, for approval or criticism by interested parties, organizations, and by Congress if it is so inclined. Full disclosure and explanation more completely and accurately inform risk managers of the results of the assessment – and this if of course entirely consistent with the overarching goal of risk assessment to provide better information for risk management decisions.

Paragraph 5 identifies three particularly important elements of transparency. First, the qualitative aspects of the risk, where relevant, need to be addressed. The harms being evaluated, the circumstances under which the risk is posed (occupational risk, for instance), the distributional qualities of the risk created (the extent to which, for example, the risk-creator

[16]EPA's internal peer review of its environmental tobacco smoke risk assessment was very rigorous and contributed to its judicial rejection. *Flue-Cured Tobacco Cooperative Stabilization Corp. v. E.P.A.*, 4 F. Supp. 2d 435 (M.D.N.C. 1998).

shares in it, or it falls uniquely on groups who may be motivated to incur it),[17] catastrophic potential, and other qualities of the risk affect managers' and the public's understanding of the risk. The chair of the Presidential/Congressional commission has said: "The descriptive and evaluative features are more important than the quantitative estimate of the magnitude of the risk or probability of occurrence. Likewise, description of the sources and significance of the assumptions and uncertainties is at least as important as any quantitative modeling of those uncertainties."[18] Qualitative assessments are particularly appropriate where data important to quantitative evaluation, such as dose response relationships in humans, are unknown or unavailable.

Second, the range of uncertainty is extremely important to understanding the nature of the risk. Thus, particularly where a high degree of uncertainty or variability persists, it is a mistake to use single point estimates. Indeed, some of the most important new developments in risk assessment methodology have been in the calculation and communication of risk ranges. Consistent with the 1971 recommendations of the Presidential/Congressional Commission on Risk Assessment and Risk Management, risk assessments should place risks into their multisource, multimedia, multichemical, and multirisk contexts, to the extent known. Risk assessors should evaluate all sources of the same or synergistic compounds or compounds with common mechanisms of action rather than limit their efforts to a single source or chemical.

Third, variability among populations, or risk distribution, is important for determining whether certain groups are at special risk. For example, risks to children and infants receive special attention in the Food Quality Protection Act of 1996,[19] and some minority groups are subject to cumulative risks or unusually high levels of exposure to hazards (*e.g.,* high fish consumption by some Native American tribes). Where such differences are likely to be significant, they should be addressed. When feasible, risk assessments should use population characteristics and exposure scenarios drawn from available data. They should identify the disproportionate effects, if any, of the regulated activity upon various subgroups, and any unique exposures or susceptibilities those subgroups may have.

6. Risk comparisons can be helpful for placing risks in context. Risk comparisons should be approached with care, particularly among dissimilar risks, and critical features of the compared risks should be fully disclosed.

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[17]Thus, Native American groups may perceive as an objective harm actions that make access to traditional places and activities dangerous.

[18]Gilbert Omenn, *Making Use of Cancer Risk Assessment*, 12:4 ISSUES IN SCIENCE & TECH. 29 (Summer 1996). About a year earlier, Gail Charnley, who was executive director of the Commission, said in an editorial letter: "Among other things, the bill calls for essentially mandatory use of risk assessment and cost/benefit analysis before a rule can take effect. Defenders of the bill seem to believe that the performance of an 'unbiased' risk assessment and cost/benefit analysis will magically make the appropriate regulatory decision apparent. Practicing risk assessors can tell you, however, that risk assessment is an imprecise tool at best. It is a useful way to organize uncertain scientific information for decisionmaking, but it is not a scientific method of assessing actual health risks." 11:4 ISSUES IN SCIENCE & TECH. 8 (Summer 1995).

[19]21 U.S.C. § 346a(b)(2).

Risk comparisons are either one of the most useful applications of risk assessment or the *reductio ad absurdum* of a quantitative process, depending on one's point of view. Risk assessment proponents believe that risk comparison permits a rational approach to regulatory priorities ("worst first") that will result in greater overall risk reduction, sooner. At a minimum, risk comparisons help to avoid perverse regulation (where the cure worsens the disease) and to avoid spending time and money on risks that are trivial by comparison with the risks inherent in everyday activities. Critics argue that risk comparisons simply multiply the already substantial uncertainties in risk assessment; in fact, the range of uncertainty or variability will often produce overlapping estimates. Risk comparison also compounds the problem of one-dimensional characterization of risk. By reducing risks to a common metric, it eliminates important qualitative differences (such as those listed above in connection with risk characterization) and results in tendentious comparisons of unlike things.

The recommendations try to stake out a principled middle ground, taking account of valid points on both sides. Comparison of alternatives is a standard and useful way to understand a situation and reach a decision, and comparisons are always about finding common denominators. This highlights some aspects of the situation and suppresses others, but this fact alone does not eliminate their utility. Moreover, in a technical and sometimes arcane area, it is often helpful to have a "reality check" against other activities. On the other hand, uncertainty and differences in risk types are undeniable.[20] As a result, simple comparative statements can obscure all kinds of judgments and assumptions under a "just the facts" terminology. As elsewhere, the recommendation's solution is not to suppress risk comparisons, because they can be valuable, but to require the exercise of judgment and full disclosure.

> *7. Public procedures associated with risk assessment should be conducted through a transparent process that allows input from and understanding of the results by persons and groups interested. Particular efforts, proportional to the overall effort involved, should be made to reach persons and groups who do not have the technical expertise to use such materials easily.*

Risk assessments involve scientific and technical methods and data, but are used to help make public (indeed, political) decisions. Therefore, a balance needs to be struck between the expert and participatory elements of the process. To some extent, this is the function of the distinction between risk assessment and risk management. Yet risk assessment decisions can have public policy components, notably in decisions about scope and underlying assumptions. As both the NAS and the Presidential/Congressional Commission have emphasized, public ("stakeholder") participation is critical to democratic decisionmaking (schematic diagrams

[20]For this reason, large-scale risk comparison projects uniformly avoid quantification. *See, e.g.,* CALIFORNIA COMPARATIVE RISK PROJECT, TOWARD THE 21ST CENTURY: PLANNING FOR THE PROTECTION OF CALIFORNIA'S ENVIRONMENT (1994); EPA, UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS (1987); EPA SCIENCE ADVISORY BOARD, REDUCING RISK: SETTING PRIORITIES AND STRATEGIES FOR ENVIRONMENTAL PROTECTION (1990).

prepared by the NAS and the Commission are attached as Figures 2 and 3). Consequently, interested and affected persons have an integral role in the assessment and management process.

The most important element of public involvement is, once again, transparency, because disclosure and explanation are the *sine qua non* of participation. The nature and extent of public involvement will naturally differ among different parts of the risk assessment process. While the public, especially the affected public, usually has a lot to add concerning scope and likely exposure scenarios; they probably have much less to contribute to choices among dose-response models and distribution functions. Neither risk analysis nor democratic decisionmaking is well served by scattershot public involvement.

> *8. Risk assessments can be useful across a broad range of agency programs and decisions. Risk assessments should be statutorily required, however, only for regulatory decisions of sufficient significance to warrant the effort. The amount of effort that goes into a risk assessment should be reasonable in relation to the significance and complexity of the decision, the value of additional information, and the need for expedition.*

Paragraph 8 expands the idea of maintaining some proportion between the degree of effort and the importance of the issue to the entire risk assessment process. Thorough risk assessment has proved to be time-consuming and expensive. Often warranted, it nonetheless also imposes opportunity costs; overdone, it deprives agencies of resources better devoted to other matters. Thus, the NAS has warned:

> Risk assessment should be adjunct to the Clean Air Act's primary goal of safeguarding public health, not an end in itself. A legitimate desire for accuracy and objectivity in representing risk can induce such an obsession with numbers that too much energy is expended on representing the results of risk assessment in precise numerical form. Thus, new research might be commissioned because there is insufficient notice of how marginal the results would be in a given case or without consideration of new, less resource-intensive methods of providing essential inputs.
>
> Moreover, there might be a vast difference between having "the truth" and having enough information to enable a risk manager to choose the best course of action from the options available.[21]

Extra time and expense can be justified when the decision is important (*e.g.,* it imposes large costs, affects many people, is unusually controversial) and the issues are complex or difficult. In such cases, and undoubtedly others, the additional effort adds real value to the regulatory process, in the sense that the additional information could make a significant difference in the resulting decision. In other cases, additional data collection and analysis will add delay and expense to the regulatory process with no commensurate gain in understanding of the situation.

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[21] SCIENCE AND JUDGMENT IN RISK ASSESSMENT, *supra*, at 260.

To address this need for proportion, paragraph 8 recommends a threshold (the executive orders on regulatory analysis use economic impact, which is probably both under- and over-inclusive for risk assessment) below which Congress should not statutorily require formal risk assessment. (No implication is intended that above that threshold, risk assessment *should* be required. As stated above, while this recommendation favors agency use of risk assessment for significant regulatory actions, it does not take a position on the question whether Congress should require it – either generally or on a statute-by-statute basis.) Paragraph 8 also recommends that in any risk assessment, the effort undertaken should be scaled to the value of the information to be obtained. The circumstances-specific judgments involved are among the most important challenges faced by those who would draft general legislation on risk assessment. In a word, the goal here is to remind risk assessors that one size does not fit all. The desirability of prompt action in the particular situation (health emergencies are the most obvious example) should also be part of this calculation.

9. Any judicial review of a risk assessment should occur only as part of the review of a final agency action for which the assessment was made.

This language associates the question of judicial review to the Section's previous positions on like analyses (notably economic impact analyses), which are already approved ABA policy. The Section believes there is no reason to revisit that issue in this context, and so has chosen a formulation that states no new principle.

Respectfully Submitted,

Ronald A. Cass
Chair

August 1999

GENERAL INFORMATION FORM

Submitting Entity: Section of Administrative Law and Regulatory Practice

Submitted By: Ronald A. Cass

1. Summary of Recommendation(s).

   This recommendation urges that in any formal requirement, promulgated by the Congress (in legislation), the President (in executive orders), or an agency head (in directives or rules), agencies of the Federal Government undertake formal risk assessments in advance of regulatory actions concerning health and safety issues consistent with certain principles.

2. Approval by Submitting Entity.

   This report with recommendation was approved by the Section of Administrative Law and Regulatory Practice Council at its February 6-7, 1999 meeting for consideration by the ABA House of Delegates in August 1999.

3. Has this or a similar recommendation been submitted to the House of Delegates or Board of Governors previously?

   No.

4. What existing Association policies are relevant to this recommendation and how would they be affected by its adoption?

   There are no relevant Association policies pertaining to support of risk assessment principles in advance of regulatory actions concerning health and safety issues.

5. What urgency exists which requires action at this meeting of the House?

   Congress has considered several bills incorporating risk assessment provisions across a wide range of environmental, safety, and health regulation. None of the bills has yet passed both houses – though risk provisions have been included in other legiislation – so the ABA needs to act now so that we may have the opportunity to help shape the present debate.

6. Status of legislation (if applicable).

Pending.

7. Cost to the Association. (Both direct and indirect costs.)

The Recommendation's adoption would not result in direct or indirect costs to the Association.

8. Disclosure of Interest (If applicable.)

There is no conflict of interest that is known to exist.

9. Referrals.

Concurrently with the submission of this report to the ABA Policy Administration Office for calendaring on the House of Delegates agenda, it is being circulated to the following ABA entities: Business Law Section; Real Property, Probate and Trust Law Section; Section of Natural Resources, Energy, and Environmental Law; Section of Texation; Section of Public Utility, Communications and Transportation Law; Lawyers Conference, Judicial Division; Section of Antitrust Law; Section of Public Contract Law; Section of Health Law; Section of Labor and Employment Law; State and Local Government Law Section

10. Contact Person (Prior to meeting.)

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11. Contact Persons. (Who will present the report to the House.)

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12. Contact Person Regarding Amendments to this Recommendation.

No proposed amendments are known to exist.

EXECUTIVE SUMMARY

1. Summary of the recommendation.

   This recommendation urges that in any formal requirement, promulgated by the Congress (in legislation), the President (in executive orders), or an agency head (in directives or rules), agencies of the Federal Government undertake formal risk assessments in advance of regulatory actions concerning health and safety issues consistent with certain principles.

2. Summary of the issue which the recommendation addresses.

   This recommendation provides an opportunity for the American Bar Association to take a position on the role of risk assessment in agency decisionmaking. Legislation under serious consideration in Congress would require agencies to make more extensive use of risk assessment and to follow certain guidelines in conducting risk assessments; it does not seek to replace substantive standards contained in the numerous statutes to which the risk assessment requirement would apply. Adoption of this recommendation would allow the ABA the opportunity to help shape the debate on this issue.

3. Please explain how the proposed policy position will address the issue.

   The proposed recommendation urges agencies of the Federal government to undertake formal risk assessments in advance of regulatory action concerning health and safety issues consistent with a set of priniciples.

4. Summary of any minority views or opposition which have been identified.

   No opposition is known to exist.