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In recent years, there has been a surge in public concern about risks to life and health, especially carcinogenic risks, as a result of technological advances. The federal role in risk management has grown along with the extent of public concern. In the last decade, the debate about federal risk management and the legislative proposals for change have centered on issues of consistency and predictability of decision-making. The author reviews the current federal regulatory framework and then analyzes proposals pending in the Congress for change in federal risk management. The author concludes that recent legislative proposals for centralization of scientific fact-finding would not result in greater consistency and predictability, and that agency coordination and use of scientific advisory panels offer less dramatic, but more realistic, approaches for improving the management of risk.

INTRODUCTION

The analysis of decision-making, weighing our available choices, analyzing our goals, and assessing which choice is most likely to lead to the chosen goal, is a process we all do, all the time. As individuals, we assess risks on an *ad hoc* intuitive basis. As a society, we assess risks on an institutional basis. Federal regulatory agencies have specific responsibilities for assessing and managing risks in licensing

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new drugs,[1] permitting discharges of air pollutants[2] and water pollutants,[3] regulating the transportation of hazardous wastes,[4] and regulating the introduction of new consumer products.[5] The process of risk assessment applies to decision-making generally, as well as to regulatory decision-making in the context of substances which may be hazardous to life, health, or the environment.

Risk management,[6] whether categorized within the rubric of regu-

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1. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (1976).
2. The Clean Air Act, 42 U.S.C. § 7401 *et seq.* (1982).
3. The Federal Water Pollution Control Act, 33 U.S.C. § 1251 *et seq.* (1980).
4. The Hazardous Materials Transportation Act, 49 U.S.C. § 1801 *et seq.* (1976).
5. The Consumer Product Safety Act, 15 U.S.C. § 2051 *et seq.* (1982).
6. The term "risk management" is used in this article to mean the overall process of evaluating and designing alternative regulatory options and selecting among them, based on consideration of relevant political, social, economic, and technical information.

The term "risk assessment" means the characterization of potential adverse health effects of varying exposures. The risk assessment process has been described as four major steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. A risk assessment might stop with the first step, hazard identification, if no adverse effect is found or if an agency elects to take regulatory action without further analysis, for reasons of policy or statutory mandate.

Of the four steps, *hazard identification* is the most easily recognized in the actions of regulatory agencies. It is the process of determining whether there has been exposure to a condition (cancer, birth defect, etc.). It involves characterizing the nature and strength of the evidence of causation. Although the question of whether a substance causes cancer or other adverse health effects is theoretically a yes-no question, there are few chemicals on which the human data are definitive. Therefore, the question is often restated in terms of effects in laboratory animals or other test systems, e.g., "Does the agent induce cancer in test animals?" Positive answers to such questions are typically taken as evidence that an agent may pose a cancer risk for any exposed humans.

Dose-response assessment is the process of characterizing the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent. It takes account of intensity of exposure, age, pattern of exposure, and possibly other variables that might affect response, such as sex, lifestyle, and other modifying factors. A dose-response assessment usually requires extrapolation from high to low dose and extrapolation from animals to humans.

Exposure assessment is the process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment. In its most complete form, it describes the magnitude, duration, schedule, and route of exposure; the size, nature, and classes of the human populations exposed; and the uncertainties in all estimates. Exposure assessment is often used to identify feasible prospective control options and to predict the effects of available control technologies on exposure.

Risk characterization is the process of estimating the incidence of a health effect under the various conditions of human exposure described in exposure assessment. It is performed by combining the exposure and dose-response assessments.

Risk Assessment in the Federal Government: Managing the Process, National Research Council, Committee on the Institutional Means for Assessment of Risks to Public Health, (National Academy Press 1983) [hereinafter cited as *Risk Assessment in the Federal Government*].

Both terms are often given more limited and more expansive interpretations. For example, H.R. 4192, discussed *infra* text accompanying note 94 provides several different definitions. Title I provides a definition of risk analysis as "the process of quantification, as much as possible, of the probabilities of an identified risk"; and a definition of risk

latory reform or seen as a substantive issue in the management of potentially hazardous substances, is of current and considerable interest in the Congress.[7]

In recent decades, public concern about risks to human life and health has surged as a result of technological advances. A 1980 Harris Poll[8] indicated that 78% of those polled believed there was more risk in day-to-day living today than in the past. Fifty-five percent believed that risks to society from scientific and technological advancement will be even greater in the future.

Several hypotheses have been advanced to explain increased public concern.[9] Technological advances have resulted in more reliable testing methods, instruments, and procedures. These detect potentially hazardous substances at lower concentrations. Advances in detection methods have revealed the extent of the environmental health problem. There has been increasing recognition of the problems associated with smaller exposures over the long term. Simultaneously, the major historical risks of disease and starvation have been made more manageable. As a result, attention has turned to reducing risks that are less immediately obvious.

The federal role in risk management has grown with the extent of public concern. Through the late nineteenth and early twentieth centuries, the dominant perception was of threat to man from his environment, not from technology. By the decades of the sixties and seventies, a new perception had emerged. Events such as the publication of Rachel Carson's *Silent Spring* in 1962, and disasters like the oil spill in Santa Barbara, California in 1969, forced the nation to examine the hidden costs of technological development. Environmental concerns prompted the enactment of various statutory measures[10]

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evaluation as "the process of judging and acceptability of various levels of risk to individuals, society, or the environment"; and a definition of risk assessment as "the total process, including both risk analysis and risk evaluation."

Title II provides a definition only of risk analysis, as "the scientific process of evaluating data to identify hazards and related risks, and includes risk characterization and (to the extent feasible) the quantitative analysis of risks."

7. Risk assessment legislation is discussed in text accompanying notes 29-50.

8. Risk in a Complex Society. A Marsh & McLennan Public Opinion Survey, conducted by Louis Harris and Associates, Inc. (New York 1980).

9. For extensive discussion of the historical evolution of public concerns about risk, see *Risk Assessment in the Federal Government*, *supra* note 6; *Public Policy, Science and Environmental Risk*, Brookings Dialogues on Public Policy, Brookings Institution (Wash., D.C. 1983); Rowe, *Governmental Regulation of Societal Risks*, 45 GEO. WASH. L. REV. 944 (1977).

10. For example: National Environmental Policy Act, 42 U.S.C. § 4321 (1977); Poison Prevention Packaging Act, 15 U.S.C. § 1471 (1982); Occupational Safety and

aimed at assessing and controlling risks to human health and the environment. Due to the levels of public concern and technical competence, previous regulatory programs had focused on short-term, immediate risks.[11] These programs used routine, short-term, acute animal studies to establish "no-observed-effect" doses and then calculated allowable human exposures.[12] But the legislation of the sixties and seventies began to reflect the introduction of more reliable testing methods. These resulted in broader government testing regulations, covering more suspect chemicals.

The decade of the seventies was characterized by a search for institutional solutions and by a growing perception of the need to balance risks and understand costs. This led to the establishment of the Environmental Protection Agency (EPA)[13] and the Occupational Safety and Health Administration (OSHA)[14] in 1970, followed by the Congressional Office of Technology Assessment in 1972.[15] The most striking feature of this new commitment to assessing and managing risk was a coordinated federal approach.

Simultaneously, Congress perceived the need to accommodate costs and benefits. The enactment of the National Environmental Policy Act (NEPA)[16] in 1969, with its far-reaching directives to understand and balance consequences through cost-benefit analysis, evidences that trend. Absolutist, cost-oblivious legislation characterized the early seventies. In the late seventies Congress made balancing directives more explicit and specified the factors to be weighed.[17]

As we reach the mid-eighties, many landmark environmental protection laws have been enacted.[18] Now, when public concern about

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Health Act, 29 U.S.C. § 651 (1975); Clean Air Act, 42 U.S.C. § 740 (1982); Federal Railroad Safety Act, 45 U.S.C. § 421 (1972); Lead Based Paint Poisoning Prevention Act, 42 U.S.C. § 4801 (1983), National Cancer Act, 42 U.S.C. § 281 (1982); Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 135 (1980); Consumer Product Safety Act, 15 U.S.C. § 2051 (1982); Marine Protection, Research and Conservation Act, 16 U.S.C. § 1431 (1974); Ports and Waterways Safety and Health Act, 33 U.S.C. § 1221 (1978); Federal Water Pollution Control Act, 33 U.S.C. § 1251 (1980); Marine Protection Research and Sanctuaries Act, 33 U.S.C. § 1401 (1980); Noise Control Act, 42 U.S.C. § 4901 (1983); Endangered Species Act, 16 U.S.C. § 1531 (1974); Safe Drinking Water Act, 42 U.S.C. § 300 (1982); Rail Safety Improvement Act, 45 U.S.C. § 39 (1975); Hazardous Materials Transportation Act, 49 U.S.C. § 1801 (1976); Toxic Substances Control Act, 15 U.S.C. § 2601 (1982); Solid Waste Disposal Act, 42 U.S.C. § 6901 (1982); Resource Conservation and Recovery Act, 42 U.S.C. § 6921 (1982).

11. *Risk Assessment in the Federal Government, supra* note 6, at 9.

12. *Id.*

13. Reorganization Plan No. 3 of 1970, 3 C.F.R. § 1072 (1966-70 Compilation), *reprinted in* 5 U.S.C. app. at 609 (1970).

14. The Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 553, 651-678 (1975).

15. The Technology Assessment Act of 1972, 2 U.S.C. §§ 471-481 (Supp. v. 1975).

16. 42 U.S.C. § 4321 (1977).

17. *See infra* text accompanying notes 39-50.

18. For example: National Environmental Policy Act, 42 U.S.C. § 4321 *et seq.*

the risk of cancer is especially acute, and when the result of a particular regulatory decision may affect human life, health, or the environment, the debate about regulatory decision-making centers on *implementation* of those laws and on the risk management *process* generally.

Much of the debate has focused on issues of consistency and predictability of decision-making.[19] We rely on our own internal values to ensure consistency in individual decision-making. In an institutional setting, consistency is sought through various mechanisms, such as, statutory prescriptions, congressional oversight, agency peer review, interagency coordination, and judicial review. Recent proposals for change, however, are based on the belief that these mechanisms are not enough—that centralization of risk assessment, with a different mechanism for receiving and weighing available information, would result in more reasoned decision-making.

Among the risks inherent in substances regulated by the federal government, no risk is more feared by the public than the risk of cancer. The ethylene dibromide (EDB) controversy in early 1984,[20] and recent disclosures about the EPA's proposal to allow residues of

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(1977); Clean Air Act, 42 U.S.C. § 740 *et seq.* (1982); Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 135 *et seq.* (1980); Federal Water Pollution Control Act, 33 U.S.C. § 1251 *et seq.* (1980); and Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq.* (1982), to name only a few of the most important laws relating to the environment.

19. For discussion of the problems in the current framework for risk management, see *Risk: Acceptability and Management*, Report by Congressional Research Service (CRS) for the House Subcommittee on Science, Research and Technology (Nov. 1981); *Risk Assessment in the Federal Government, supra* note 6; *Risk/Benefit Analysis in the Legislative Process*, Summary of a Congress/Science Joint Forum by CRS for the House Subcommittee on Science, Research and Technology and the Senate Subcommittee on Science, Technology and Space (March 1980); Rodgers, *Benefits, Costs and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENVTL. L. REV. 191 (1980); McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729 (1979); Rowe, *Governmental Regulation of Societal Risks*, 45 GEO. WASH. L. REV. 944 (1977); Kraft, *The Use of Risk Analysis in Federal Regulatory Agencies: An Exploration*, 1 STUD. POL'Y REV. 666 (1982); Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025 (1983); Regens, Dietz, & Ryecroft, *Risk Assessment in the Policy-Making Process: Environmental Health and Safety Protection*, 43 PUB. AD. REV. (1983).

20. Articles about ethylene dibromide (EDB) headlined the Washington Post, the New York Times, and many other publications. On October 1, 1983, for example, the Washington Post announced the banning of EDB as a soil fumigant. By January 11, 1984, the Washington Post had reported that emergency meetings were being held to map out a strategy for EDB, and that EDB may have "tainted" nearly all of the nation's 7.7 billion bushel grain stockpile. On January 21, 1984, the New York Times lead editorial dealt with the EDB crisis.

a potentially cancer-causing substance in chicken eggs and meat attests to the extent of the problem.[21]

This article, while examining and critiquing proposals pending in the Congress for the way we manage risk generally, focuses particularly on regulation of substances which are potentially carcinogenic and on the risk of cancer.

In Part I, the article reviews the current federal framework for regulation of such substances. In Part II, the article explores recent legislative proposals for centralizing the federal risk assessment role in a single entity. In Part III, the article critiques these proposals for change, raising issues of legal and political feasibility. Finally, in Part IV, alternative ideas are suggested for handling risk management at the federal level.

Current Framework for Management of Risk

The current federal framework for assessing and managing risks from exposure to substances that may be carcinogenic[22] is complex and fragmented. There are many actors in the process, each involved in some aspect of the overall management of risk.

The Congress and the executive branch influence the risk assessment process through legislation and the annual budgetary process. In its legislative and oversight role, Congress is engaged primarily in a non-technical review of "scientific facts," often, but not always, followed by legislative direction to the agencies. In this endeavor, Congress has several committees which frequently investigate scientific issues.[23]

The primary vehicle for "in-house" congressional investigation is the congressional hearing process. Whether used as oversight for authorization of agencies, investigative forums, or preparatory to the committee mark-up of legislation, hearings have been criticized as not conducive to the clarification and resolution of scientific disputes.[24] Indeed, because the hearing process takes place in a politically-charged setting in which goals are likely to have been defined

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21. Washington Post, May 3, 1984.

22. The term "carcinogen" is used to describe any agent that induces or tends to induce cancer in man or animal, irrespective of mechanism. *Public Policy, Science and Environmental Risk*, 45 Brookings Dialogues on Public Policy, Brookings Institution (Wash., D.C. 1983), quoting from Committee of the Health Council, Ministry of Health and Environmental Protection, *The Evaluation of the Carcinogenicity of Chemical Substances* (The Hague: GPO, 1980).

23. The Senate Committee on Commerce, Science and Transportation, Subcommittee on Science, Technology and Space, the Senate Committee on Labor and Human Resources, and the House Committee on Science and Technology are involved in investigation of current science, technology, and health issues.

24. For discussion of the limitations of the congressional hearing process in the science setting, *see* Martin, *Procedures for Decisionmaking Under Conditions of Scientific Certainty: The Science Court Proposal*, 16 Harv. J. on Legis. 443, 468-71 (1979).

from the outset, hearings rarely provide a backdrop for fine-tuning of controversial issues. For in-depth analysis, Congress also has available the resources of the Office of Technology Assessment (OTA),[25] the Congressional Research Service (CRS),[26] and the General Accounting Office (GAO)[27] to aid in description and assessment of particular scientific issues.

With the exception of politically explosive issues that may be removed from agency discretion by Congress,[28] the major responsibility for assessing risks and selecting regulatory options falls upon the agencies. Their discretion is constrained by statutory directives, the degree of specificity in such legislation, and their own resources and practices.

Statutory Approaches

The extent to which agencies use a formal process of risk assessment[29] depends, in part, on the legislative authority for regulating the use of a particular substance in question. Statutory schemes for allocating the burden of proof affect the nature of the agency risk assessment process. For example, the EPA administers several laws requiring substances be proven hazardous before regulation.[30] However, they do not authorize the EPA to require industry to provide risk assessments. But the EPA is also responsible for the administration of laws which allow the EPA to require industry to provide risk assessments before substances can be used commercially.[31] The Food and Drug Administration (FDA) can require manufacturers to perform risk assessments demonstrating the safety and effectiveness of new drugs, and the safety of additives and other substances ingested as food.[32] But under its regulatory authority for cosmetics, the FDA has the burden of assessing the risks of a particular substance prior to regulatory action.[33]

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25. The Technology Assessment Act of 1972, 2 U.S.C. § 471 *et seq.* (Supp. v. 1975).
26. The Legislative Reorganization Act of 1970, 2 U.S.C. § 166 (1977).
27. The General Accounting Office Act of 1974, 31 U.S.C. § 701 *et seq.* (1983).
28. *See* discussion of the saccharin controversy, *infra* note 36.
29. *See supra* note 6.
30. For example, the Clean Air Act, 42 U.S.C. § 740 (1982); the Federal Water Pollution Control Act, 33 U.S.C. § 1251 (1980); the Safe Drinking Water Act, 42 U.S.C. § 300 (1982); and the Resource Conservation and Recovery Act, 42 U.S.C. § 6921 (1982).
31. For example, the Toxic Substances Control Act, 15 U.S.C. § 2601 (1982).
32. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (1976).
33. *Id.*

Statutory approaches to risk management have been variously catalogued. One useful categorization divides the regulatory scheme for potential carcinogens into three classes:[34] statutory schemes which prohibit any risk; statutory schemes which consider only technological feasibility in regulating risk; and statutory schemes which implicitly or explicitly call upon the agencies to balance risks, costs, and benefits.

No-Risk Standard

The first category, prohibition of any risks, is best exemplified by the Delaney amendment to the Food, Drug and Cosmetic Act,[35] in which any indication of carcinogenicity will trigger a specific policy outcome. The no-risk category is notable for its unintended, as well as intended, results. Because agencies operating under this statutory scheme have no discretion to weigh costs and benefits, agency decision-making is mandated by the rigidity of the law. Thus, where the result would be contrary to popular sentiment, Congress may be forced to legislatively carve out exceptions to the rule.[36] Clearly, one motive for the absolute prohibition in the Delaney amendment is the perception that food additives and colorings have insufficient countervailing benefits to justify any risk of cancer. Implicitly, in the Delaney Clause, Congress has made a judgment that the benefits of requiring zero-risk outweigh the costs in the majority of cases. In this category of legislative response to potential risk, the risk assessment process plays a limited role. Once the hazard has been identified as present, the scientific findings trigger the policy outcome.

Technological Feasibility

The second category, consideration of technological feasibility, is an interesting statement about belief in the powers of technology and about recognition of its limits. Rather than prescribing a goal *per se* (in comparison to the Delaney Clause where the goal is non-carcino-

34. *See* Office of Technology Assessment, *Technologies for Determining Cancer Risks from the Environment*, 1981; Field, *Statutory and Institutional Trends in Government Risk Management: The Emergence of a New Structure*, Report prepared for Committee on Risk and Decisionmaking, National Academy of Sciences (unpublished), adapting and reprinting portions of a table from Trauberman, *Comparison of FDA Food Safety Regulation with Regulation of Other Environmental Hazards*, appendix C to Institute of Medicine, *Food Safety Policy*, Washington D.C.: National Academy of Sciences, 1979, and Toxic Substances Program, Environmental Law Institute; *Cost Benefit Analysis and Environmental, Health and Safety Regulation: An Overview of the Agencies and Legislation* (paper presented for the Environmental Law Institute, 1980).

35. Food, Drug and Cosmetic Act, 21 U.S.C. § 348 (c)(3)(A) (1976).

36. Thus, because testing at the FDA had demonstrated the risk of carcinogenicity in saccharin, the Delaney Clause mandated removal of the substance from the market. However, due to public outcry, Congress stepped into the controversy and legislatively overruled the FDA. Pub. L. No. 96-273.

genicity in additives), these legislative standards are based on the capability of technology to control a specific risk. Yet, as with the first category, the agencies cannot consider cost. Nor can they consider whether use of the best available technology will result in a net reduction in risk. Standards are promulgated on the basis of the latest scientific and technological knowledge. For example, both the Clean Water Act[37] and the Clean Air Act[38] require that technological factors be given exclusive consideration.

Use of risk assessment in this category of risk statutes is again constrained. Under this type of statute, an agency's risk analysis can usually be limited to an investigation of (a) the presence or absence of a given risk source (hazard-identification) and (b) the range of practicable and/or available control technologies.

Balancing Factors

A third category, balancing of risks, costs, and benefits, represents the dominant trend.[39] Here the agency's discretion as to what weight to accord the variables may be quite broad, as in, for example, the Consumer Product Safety Act (CPSA).[40] In the CPSA, the legislative directive to the agency is for the promulgation of rules "reasonably necessary" to reduce an "unreasonable risk of injury."[41] It is up to Commission discretion to flesh out the meanings of "reasonable" and "unreasonable," as well as the meaning of "necessary."

A more explicit balancing statute is the Toxic Substances Control Act (TSCA).[42] Under TSCA, the EPA is directed to control substances presenting an unreasonable risk of injury to health or the environment.[43] While the EPA is given a range of regulatory options, it is required first to publish an analysis of its findings regarding the costs and benefits of the regulatory option *and* the substance. This also includes the impact, among other factors, upon small business, technological innovation, and public health.[44]

The Federal Insecticide, Fungicide and Rodenticide Act

37. 33 U.S.C. § 1251 *et seq.* (1980).
38. 42 U.S.C. § 7401 *et seq.* (1982).
39. *See* Rodgers, *Benefits, Costs and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENVTL. L. REV. 191 (1980).
40. 15 U.S.C. § 2051 *et seq.* (1982).
41. *Id.*
42. 15 U.S.C. § 2601 *et seq.* (1982).
43. *Id.* at § 2603(a)(1)(A)(i).
44. *Id.*

(FIFRA)[45] presents another example of more explicit directives to balance costs, risks, and benefits. Registration, limitation, or refusal to register are the primary regulatory options. These options can be pursued only after a balancing of "unreasonable adverse effects on the environment" with the economic, social, and environmental costs and benefits of the use of the pesticide in question.[46]

The balancing model, whether explicitly or implicitly enumerating factors, is the model most dependent upon a full risk assessment process. In order to meet the goals of the statute, agencies may develop new approaches to risk assessment, but the use of some risk assessment process is unavoidable. The balancing approach requires that a comparative assessment be made of relevant risks, costs, and benefits. Problems involved in identifying, quantifying, and systematically comparing such risks, costs, and benefits can be significant.

In practice, most agencies involved in risk management do not institutionally separate the assessment of risks from the evaluation of various regulatory options. Agencies may use in-house staff or they may rely on outside consultants and contracts. They may also use outside peer review, whether through *ad hoc* or standing advisory committees. Use of such advisory committees is often directly mandated by statute.[47] The degree of coordination among agencies responsible for risk assessment has also varied, depending on Administration encouragement.[48]

It is difficult to quantify the number of carcinogens present in commercial use. The regulatory agencies charged with assessing and managing the substances in common commercial use have a mammoth task.[49] In managing these substances, the agencies conduct an

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45. Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 135 *et seq.* (1980).

46. *Id.* at § 136 (bb).

47. For example, the Toxicology Advisory Board, 15 U.S.C. § 1275 (1982); the Advisory Committee on Reactor Safeguards, 42 U.S.C. § 2039 (1973); the Color Additive Advisory Committee, 21 U.S.C. § 376(b)(5)(C)(1976); the Technical Electronic Product Radiation Safety Standards Committee, 42 U.S.C. § 263f(f)(1)(A)(1982); the Air Quality Advisory Board, 42 U.S.C. § 1857(e)(1978); and the Science Advisory Board, 42 U.S.C.] 436]5 (1977), are all mandated by statute.

48. For example, during the Carter Administration, several of the key agencies cooperated through the mechanism of the Interagency Regulatory Liaison Group (IRLG). During the first year of the Reagan Administration, the IRLG effort was abandoned. But recently, similar interagency coordination is being pursued under the leadership of the EPA.

49. By most calculations, there are some five million known chemicals. Of these, about 53,500 distinct substances are regulated by the EPA and the FDA. A recent study by the National Research Council (NRC) has documented just how overwhelming a task the regulatory agencies have. According to the NRC study, no toxicity information exists for nearly 80% of the chemicals used in commercial products and processes — substances listed in the Toxic Substances Control Act inventory. Minimal toxicity information exists for the remaining 20%. The news is only slightly better for pesticides (complete health hazard assessments are possible for about 10%). *See Toxicity Testing: Strategies to De-*

initial risk assessment[50] as a priority-setting tool. If a substance is judged to have risks significant enough to warrant action, a more detailed risk assessment is conducted. The effects of different regulatory options are evaluated. In some cases, regulatory priorities are refined further. If the agency decides to proceed with regulation, that process may include agency fact-finding, an advance notice of proposed rulemaking, a regulatory proposal, public comment and hearings, a new agency proposal, and final regulation.

In examining the risk assessment approaches of agencies charged with regulation of potential carcinogens, four agencies provide the most useful study: the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), the Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA). Their practices illustrate the range of regulatory approaches. These include reliance upon outside scientific peer review, detail and formality of risk assessments through promulgated guidelines, extent of inter-agency coordination, and the dominating influence of the particular legislative scheme.

Agency Practices

Science Advisors

Use of science advisory committees, standing or *ad hoc*, for peer review of assessments prepared by the agency staff, or for actual risk assessments in the first instance, varies among the four agencies. The EPA and the FDA have the longest history with expert panels.[51]

The majority of the EPA's panels are statutorily mandated, and therefore have clearly described roles in the agency's risk management responsibilities. For example, the agency-wide Science Advisory Board (SAB), initially created by agency discretion, was formally established in 1978 by statute.[52] It was directed to review the quality of research and research planning at the EPA and to review the technical bases of EPA regulatory activities generally. The EPA uses the SAB in its regulatory process to review staff risk assessments and to address issues with a six month to one year time

termine Needs and Priorities, Steering Committee on Identification of Toxic and Potentially Toxic Chemicals for Consideration by the National Toxicology Program, Board on Toxicology and Environmental Health Hazards (National Academy Press, March 1984).

50. For a general discussion of agency experience with risk assessment, see *Risk Assessment in the Federal Government*, *supra* note 6.

51. *Id.*

52. 42 U.S.C. § 4365 (Supp. 1984).

frame.[53] The EPA turns to the National Academy of Sciences on occasion, for studies of issues of less immediate regulatory concern.[54]

The CPSC has had the shortest institutional experience with science advisory panels. The 1978 amendments to the Federal Hazardous Substances Act[55] mandated the creation of a Toxicology Advisory Board.[56] That Board advises the Commission regarding antidote and warning label instructions for acutely hazardous chemicals.[57] In addition, the 1981 reauthorization of the CPSC[58] contained a provision that before any regulatory action could be proposed on a substance potentially presenting a carcinogenic, teratogenic, or mutagenic hazard, a chronic hazard advisory panel (CHAP) had to be established with the cooperation of the National Academy of Sciences to review the toxicity of the substance.[59] Thus far, a CHAP has been convened to review the toxicity of asbestos. The Commission has voted to convene two additional CHAPs in the coming months.[60]

OSHA has had limited experience with independent science panels. Until the late 1970's, OSHA relied primarily upon the Department of Health and Human Services' National Institute of Occupational Safety and Health (NIOSH) for outside research and recommendations for occupational health standards.[61]

The FDA's experience with science advisory panels has been as extensive as, but less structured than, the EPA's. The Bureau of Drugs within the FDA has several standing advisory committees which review the safety and performance of all medicines for human use.[62] In contrast, the Bureau of Foods has used science advisory committees on an as-needed basis, setting up its own *ad hoc* panel or relying on peer-review from panels at the National Toxicology Program.[63]

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53. Conversation with Dr. Terry Yosie, Director, Science Advisory Board, Environmental Protection Agency (Dec. 21, 1983).
54. *Id.*
55. 15 U.S.C. § 1275 (1982).
56. *Id.*
57. *Id.*
58. Consumer Product Safety Act Amendments of 1981, P.L. 97-35, § 1201 *et seq.*, 95 Stat. 703-725 (1981).
59. *Id.*
60. Conversation with Sandra Eberle, Program Manager, Chemical Hazards Program, Consumer Product Safety Commission (Dec. 15, 1983).
61. Risk Assessment in the Federal Government, *supra* note 6, at 110.
62. Conversation with Dr. Allen Heim, Director, Office of Science Coordination, Food and Drug Administration (Nov. 29, 1983).
63. *Id.*

Guidelines

Agency use of guidelines establishing uniform practices has varied considerably. Guidelines, of course, vary as to comprehensiveness and flexibility (i.e., the degree to which guidelines allow one selected option to be replaced by another as a result of convincing scientific evidence). They may also vary in their legal status and procedural implications, depending upon whether they are binding regulations, established agency procedures, or merely recommendations by staff or independent peer reviewers.

In 1977, OSHA proposed generic guidelines for carcinogens.[64] After extensive hearings, the guidelines were formally promulgated as regulations in 1980.[65] However, the agency has not used the regulations as a basis for any published assessment of carcinogenic hazard. The rules were revised in 1981 as a result of the U.S. Supreme Court's benzene decision,[66] but have not been republished since then.

The EPA created, in 1976, a Carcinogen Assessment Group[67] to implement generic and uniform agency guidelines for carcinogens. These guidelines, while never published as regulations, are fairly widely accepted. They are quite general in scope and address only certain aspects of risk assessment.

The CPSC proposed cancer guidelines in 1978,[68] but these guidelines were challenged in court[69] and were held to have been illegally promulgated due to lack of public input.[70]

Inter-Agency Coordination

Formal attempts at coordination of agency approaches to risk assessment have occurred over the last decade.[71] In August 1977, the EPA, the CPSC, OSHA, and the FDA established the Interagency Regulatory Liaison Group (IRLG) to coordinate regulatory policy.

In 1979, after an 18-month inter-agency effort, the IRLG pub-

64. 42 C.F.R. § 54148 (1977).
65. 45 C.F.R. § 50002 (1980).
66. Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980).
67. *See Risk Assessment in the Federal Government, supra* note 6.
68. Policy and Procedure for Classifying, Evaluating and Regulating Carcinogens in Consumer Products, 43 C.F.R. § 25658 (1978).
69. Dow Chemical v. Consumer Product Safety Commission, 459 F. Supp. 378 (W.D. La. 1978).
70. *Id.*
71. The efforts of the IRLG, as summarized here, are drawn from a discussion in *Risk Assessment in the Federal Government, supra* note 6.

lished a report, *Scientific Bases for Identification of Potential Carcinogens and Estimation of Risk.* The report was prepared by personnel of the CPSC, the EPA, the FDA, and OSHA, with the assistance of senior scientists from the National Cancer Institute and the National Institute of Environmental Health Sciences. It was published in a scientific journal and in the *Federal Register.* The IRLG report was said to represent an inter-agency consensus on the scientific aspects of carcinogenic risk assessment. It was the most comprehensive set of guidelines that had been developed for agency use, addressing most components of hazard identification and dose-response assessment.

Almost immediately after its publication, the IRLG report was adopted by the President's Regulatory Council and incorporated as the scientific basis of the Council's government-wide statement on regulation of chemical carcinogens. The Council viewed the IRLG guidelines as a major step in reducing inconsistency, duplication of effort, and lack of coordination among agencies in carcinogenic risk assessment. However, in 1980, with the change in Administration, the IRLG was disbanded. Current sentiment in the Executive branch favors coordination. The EPA, under the direct mandate of Administrator Ruckleshaus, is now engaged in an effort, reminiscent of the IRLG, to develop guidelines for assessing carcinogenic risks.

Another inter-agency coordination effort has been underway since 1978 at the National Toxicology Program. The NTP was established in 1978 as a Department of Health and Human Services effort to coordinate the Department's toxicity testing programs and to aid in cooperation efforts among the relevant agencies. The NTP includes the toxicity testing efforts of the National Cancer Institute, the National Institute of Environmental Health Sciences, the FDA, and the Centers for Disease Control. To include the regulatory interests of other agencies, the NTP relies upon an Executive Committee, which is made up of the NTP agencies and representatives from the FDA, OSHA, the CPSC and the EPA. The NTP has reviewed risk assessments, recommended substances for testing, and published lists of known and suspected carcinogens.

Finally, the Committees of the National Academy of Sciences (NAS)/National Research Council (NRC) serve frequently as a resource for regulatory agencies. In the last five years, the NRC has issued approximately 125 reports a year in which risk assessment is an issue.[72] In more than 50 of these the NRC Committee has actually estimated or evaluated some element of risk.[73] Agencies are free,

72. *The Handling of Risk Assessments in National Research Council Reports,* Report to the National Research Council by Committee on Assessment of Risk, (March 1981) at p. 1.

73. *Id.*

however, to accept or reject the analyses and conclusions of NAS/NRC panels.

PROPOSALS FOR CHANGE IN RISK MANAGEMENT

The last five years have brought a surge of proposals in the Congress for so-called regulatory reform.[74] Many of these ideas focused on risk assessment within regulatory decision-making. Legislative and administrative proposals directed at the generic process of risk assessment began to surface with the 96th Congress.[75]

Some proposals were aimed at studying the internal risk assessment process across the agencies and arrived at recommendations for change. These proposals were justified due to the agencies' inconsistent and unpredictable use of risk assessment techniques.[76] For example, legislation offered by Representative Ritter (R-Pa.) in the 96th, 97th, and 98th Congresses would establish a coordinated set of demonstration projects under the direction of the Office of Science and Technology Policy (OSTP). These projects encourage the use of comparative risk analysis[77] by a number of federal agencies involved in health and safety regulation.[78]

Ritter's bills were designed, in part, to inform the Congress how federal agencies are carrying out existing mandates regarding risk. None of his proposals would affect the content of any existing law.

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74. In recent years, these proposals have addressed issues such as establishing a regulatory budget to control the costs of federal regulation, use of cost-benefit analysis in rulemaking, sunset provisions, legislative veto, and presidential veto of rulemaking.

75. *See Risk: Assessment, Acceptability and Management*, Report by CRS for the House Subcommittee on Science, Research, and Technology Subcommittee (Nov. 1981); *Risk/Benefit Analysis in the Legislative Process*, Summary of a Congress/Science Joint Forum by CRS for the House Subcommittee on Science, Research and Technology and the Senate Subcommittee on Science, Technology and Space (March 1980). Proposals for generic change in risk assessment include H.R. 4939 and H.R. 8303 (Ritter), H.R. 6521, and H.R. 638 (Wampler). Judicial interpretations of the National Environmental Policy Act (NEPA) to include formal cost-benefit analysis make NEPA an early influence in the evolving process of agency use of quantitative risk assessments. *See* Calvert Cliffs' Coordinating Comm. v. AEC, 449 F. 2d 1109 (D.C. Cir. 1971).

76. *See* 129 CONG. REC. E4052 (Aug. 4, 1983) (Statement of Rep. Ritter).

77. Representative Ritter's bills define comparative risk assessment as: "a procedure in which the assessment of the risks associated with one course of action and the assessment of the risks associated with an alternative course or courses of action are compared with each other and with the kinds of risks people normally face in their individual lives." H.R. 4192 Title I. Sec. 104(e).

78. In the latest version of the Ritter proposal, eight agencies are specified: the Food and Drug Administration, the Environmental Protection Agency, the Occupational Safety and Health Administration, the Food Safety and Inspection Service of the Department of Agriculture, the Nuclear Regulatory Commission, the Department of Energy, the Consumer Product Safety Commission, and the Department of Transportation.

The projects would be conducted in two parts. The first twelve-month study would be an overview of existing risk assessment procedures, a review of necessary research, and a proposal for the demonstration projects to follow. This segment would be summarized in a report to Congress twelve months after enactment of the bill. During the second twelve months the demonstration projects would be conducted and the results made available to experts in the field for critical peer review as well as the public at large. The second segment of the study would be reported to Congress within thirty months after the enactment of this act. The final report to Congress would contain recommendations for improvement of risk assessment, and for needed research and legislative and organizational change. Comparable legislation was also introduced in the Senate.[79] In the 97th Congress, the House passed the Ritter bill, but the full Senate did not act on its legislation.

Proposals for Centralization

Other proposals would centralize the risk assessment and, in some cases, risk management function, in a single entity. Proponents of centralized risk assessment based their proposals on two features of the current framework which they believe can be changed: 1) lack of separation of scientific fact-finding from policy judgments; and 2) lack of coordination in risk management among the agencies.

Lack of institutional separation of the scientific component of risk assessment from policy choices is said to be manifested in a number of ways.[80] First, the scientific members of peer-review and science advisory panels are said to be biased by virtue of their very selection. It is suggested that members of these panels are selected because of their expertise, but that such expertise necessarily results in members having preconceived ideas and agendas. Second, the recommendations of science advisory panels are said to be tainted by value

79. In the 97th Congress, Senator Schmitt introduced S. 3006, a companion bill to H.R. 6159.

80. For analysis of proposals for centralized risk assessment, particularly the Science Court concept, see Martin, *Proposed "Science Court"*, 75 MICH. L. REV. 1058 (April-May 1977); *Risk Assessment in the Federal Government: Managing the Process*, National Research Council, Committee on the Institutional Means for Assessment of Risks to Public Health, National Academy Press (1983); Kantrowitz, *Controlling Technology Democratically*, 63 AM. SCIENTIST 509 (1975); Martin, *Procedures for Decision-making Under Conditions of Scientific Certainty: The Science Court Proposal*, 16 HARV. J. ON LEGIS. 443 (1979); *Risk: Assessment, Acceptability and Management*, Report by CRS for the House Subcommittee on Science, Research, and Technology (Nov. 1981); Sofaer, *The Science Court: Unscientific and Unsound*, 9 ENVTL. L. 1 (1978); Banks, *The Science Court Proposal in Retrospect: A Literature Review and Case Study*, 10 CRITICAL REVIEWS IN ENVTL. CONTROL 95 (1980); *The Science Court Experiment: An Interim Report*, Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, 193 SCI. 653; Markey, *A Forum for Technocracy: A Report on the Science Court Proposal*, 60 JUDICATURE 364 (1977).

judgments, both in the generally conservative choice of inference options and because science advisory panel members may develop close working relationships with decision-makers and thus end up advising on the final *policy* aspects of a decision.

Proponents of centralized risk assessment also argue that the traditional deference paid to findings of independent science advisory panels further exacerbates the adverse impact of failure to separate scientific fact-finding from value judgments. Moreover, they believe the pressure within science advisory panels to reach consensus decisions prevents the public from receiving accurate information about the scientific issues in dispute.

Lack of a coordinated, consistent, and, above all, predictable regulatory process is a common theme as well. Agency jurisdiction under particular statutory schemes overlaps,[81] and agency jurisdiction over particular substances overlaps.[82] Treatment of the same substance can vary from agency to agency,[83] as differing statutory schemes and goals are applied. The result, critics charge, is an incomprehensible, unpredictable hodge-podge of regulation.[84]

Past and present efforts at coordination among the agencies are criticized as too limited, or in some cases, too conservative. Critics also charge that overzealous administrators fuel public concern by neglecting to emphasize the tentative nature of the scientific findings leading to policy choices. Finally, critics charge that while science advisory panels perform a valuable function in bringing independent peer-review to the regulatory process, the panels lack public accountability and often lack a clear understanding of the limits of their task.

Proponents of centralized risk assessment believe that centralization would enhance the accuracy of scientific information, limit the power of scientists, eliminate the opportunity for policymakers to hide policy decisions behind scientific conclusions, and publicly identify discredited scientific claims.[85] Their solution is a process that

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81. For example, formaldehyde is regulated by the Consumer Product Safety Commission as insulation under authority of the Consumer Product Safety Act; the Environmental Protection Agency regulates formaldehyde as a chemical under authority of the Toxic Substances Control Act.

82. *Id.*

83. *Id.*

84. *See supra* text accompanying notes 80-82.

85. *See* Kantrowitz, *Controlling Technology Democratically*, 63 AM. SCIENTIST 509 (1975). Markey, *A Forum for Technocracy: A Report on the Science Court Proposal*, 60 JUDICATURE 364 (1977); *The Science Court Experiment: An Interim Report*, Task Force of the Presidential Advisory Group on Anticipated Advances in Science and

formally separates fact-finding from value judgment. The Task Force Science Court[86] even relies upon a traditional adversary system to delineate areas of controversy.

Science Court

Presaging legislative proposals for a centralized entity has been the long-standing debate about establishment of a formal science court. As proposed by the Presidential Task Force on Anticipated Advances in Science and Technology, the Science Court concept was an ambitious and far-reaching idea. It incorporated legal concepts into a framework for assessing scientific facts. The Task Force proposal envisioned a three-judge panel of impartial scientists. These judges would hear testimony on both sides of an issue presented by "case managers," who would be scientific experts chosen by their peers. At the proceeding, case managers would formulate a series of statements of scientific fact based on experimental data and inferences drawn from the data. Statements accepted by both sides would be compiled and published. Statements in controversy would be subjected to a round of mediation.

The remaining challenged statements would be subjected to an adversary process of cross-examination by the opposing case manager and judges. After a second round of mediation, judges would write an opinion on the remaining contested statements. They would delineate areas of scientific uncertainty, areas requiring further research, and areas of agreement. The judges' report would not contain any policy recommendations.

The proponents of the Science Court concept stressed three key presumptions:[87] 1) It is both desirable and possible to separate "scientific facts" from "value judgments," 2) Uncertainties regarding controverted questions of scientific fact can be resolved through an adversary process, separating advocate from judge, 3) Disputed scientific issues can best be resolved in a public forum, followed by written publication.

The goal of the Science Court as proposed by the Task Force was not to arrive at "truth." Rather, it was to describe the current state of technical knowledge, to refine areas of uncertainty, and to indicate

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Technology, 193 SCI. 653; Kantrowitz, *The Science Court Experiment: Criticisms & Responses*, 33 BULL. ATOM. SCIENTISTS 44 (April 1977).

86. *The Science Court Experiment: An Interim Report*, Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, 193 SCI. 653.

87. *See The Science Court Experiment: An Interim Report*, Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, 193 SCI. 653; Kantrowitz, *Controlling Technology Democratically*, 63 AM. SCIENTIST 509 (1975); Kantrowitz, *The Science Court Experiment: Criticisms & Responses*, 33 BULL. ATOM. SCIENTISTS 44 (April 1977).

areas of needed research to aid regulatory decision-makers.[88] Legislative proposals for a centralized decision-making entity have paralleled the Task Force proposal in many ways.

National Science Council

Legislation introduced by Representative Wampler in both the 96th and 97th Congresses was aimed at centralizing the risk assessment and risk management function in a National Science Council. The Council, functioning as a Science Court of sorts, would decide on questions of scientific fact prior to any agency decision-making. Wampler envisioned a standing body of fifteen members, housed in the National Science Board. This body would hold hearings on the record and decide any question "of scientific fact arising in an agency adjudication involving the harm any substance may cause to human health,"[89] which was duly referred to the Council. Under the bill, any party could request referral of scientific issues to the Council. Amendments to seven major regulatory statutes[90] to mandate referral to the Council were included in Wampler's bill.

The Council would base its decision on a particular question on the report of an advisory hearing panel. If the question specifically involved an "evaluation of risk of harm to human health,"[91] the bill required the panel report to include: a summary of related scientific test observations with an evaluation of their validity; an analysis of the quality and quantity of related scientific information available; a description of groups bearing the greatest risk burden; and an advisory opinion "characterizing the level of risk to human health."[92] The Council was required to issue a decision, either final or tentative, within ninety days after the date a question of scientific fact was referred to the Council. The Council's decisions would be binding on the agencies.

The Wampler bill was not acted upon during the 97th Congress. But, the Wampler bill had closely tracked an industry proposal for centralization of agency risk assessments. That proposal, in revised form, surfaced again during the 98th Congress. Since 1979, the industry lobbying group, the American Industrial Health Council

88. *Id.*
89. H.R. 638, Sec. 5, 97th Cong. (introduced Jan. 5, 1981).
90. *Id.* at Sec. 18.
91. *Id.* at Sec. 7(C)(2).
92. *Id.* at Sec. 7(C)(2)(E).

(AIHC), had advanced various proposals[93] for an expert science panel, in which independent scientists would be used and risk assessment would be separated from risk management. The AIHC proposal has some interesting wrinkles. Although any party could request review, only federal agencies or Congress could initiate mandatory review. Decisions of the AIHC-envisioned panel would not be binding on the agencies. However, failure to follow the recommendations would have to be explained in written, published form. The AIHC panel would be housed in the National Academy of Sciences.

Central Board

In the 98th Congress, a bill pending in the House of Representatives embodies many of the presumptions and features of prior "science court" proposals. Originally introduced as two separate bills, the pending version of H.R. 4192 has two very distinct titles, each containing a separate bill. Title I, as introduced by Representative Ritter, restates his past proposals to develop a coordinated, systematic approach to the use of risk assessments through demonstration projects, coordinated by an agency designated by the President.

Title II, originally introduced by Representative Martin (R-N.C.) as a separate bill,[94] has a distinctly different flavor. Rather than study, experiment with, and critique the process of risk assessment, Title II assumes the need for change and creates it. Title II envisions the establishment of a Central Board of Risk Assessment, within the NAS/NRC, comparable to the Wampler Science Council and to the Task Force Science Court, but more limited. The duties of the Board would be: 1) to develop, issue, and revise scientific principles and practices for risk analysis (defined as the process of evaluating data to identify hazards and risks) reflecting the current state-of-art; and 2) to selectively review risk assessments made by federal agencies or establish subpanels to carry out that function.

The Board would carry out its review duties whenever: 1) a federal agency proposed to make a regulatory decision or take an action based on a risk assessment; and 2) such risk assessment was deter-

93. The American Industrial Health Council was established in 1977 to react to federal regulatory efforts with regard to carcinogens.

The AIHC has been very active since its inception. On February 24, 1978, the AIHC recommended alternatives to OSHA's Generic Carcinogen Proposal. On May 5, 1979, the AIHC submitted draft comments on a report of the IRLG workgroup on work assessment. On September 11, 1978, the AIHC presented its guidelines for evaluation and use of occupational epidemiologic cancer studies. In October 1979, the AIHC proposed a detailed framework for federal identification and regulation of carcinogens. In December 1979, the AIHC formed a Science Panel Task Force to develop a formal proposal recommending the establishment of an independent and centralized Science Panel. The Wampler bill was introduced in February 1980.

94. H.R. 3976.

mined by the agency to involve scientific issues of national importance; and 3) both the directors of OSTP and the NAS agreed that it involved scientific issues of national importance.

The Board, presumably acting as an appellate body, would review the agency analysis and prepare a written report. The report would not be binding on the agencies. If the agency failed to act in accordance with the Board's report, it would be required to publish in the *Federal Register* a complete explanation and justification for its contrary action.

CRITIQUE OF PROPOSALS FOR CHANGE

Proposals for change focus on two approaches: a) study and demonstration projects, followed by recommendations to Congress, e.g., Ritter's Title I of H.R. 4192; and b) centralization of the risk assessment function in a single entity, e.g., Martin's Title II of H.R. 4192, the Task Force Proposal for a Science Court, and the Wampler bills. The premise of the first approach is the need for further information on the use of risk assessment by federal agencies. The second approach is based on the belief that centralization is the key to addressing concerns about the current system. Proponents of centralization argue the current federal system for managing risk fails to separate scientific fact-finding from value judgments, thereby fatally tainting the results, and the current system is fragmented and redundant, leading to inconsistent and unpredictable decision-making.

Limitations of Risk Assessment

Some of this criticism is misplaced. To some extent, it is not agency implementation of legislative mandates, incidentally requiring risk assessments, that has caused the problem. Rather, the risk assessment process itself is inherently limited. The risk assessment process has been politicized because of the ultimate regulatory outcomes. However, little attention is paid to the techniques, limits, or appropriate use. Risk assessment can tell us something about approaching risk in an economically-efficient way. It can give us quantitative data on how different risks affect different groups. Risk assessment can also be used to compare similar risks to each other.

Risk assessment as a technique leading to decision-making has extremely important limitations. Regarding carcinogens, the data base currently lacks significant information on toxicity and exposure. This is partially due to the sheer number of chemicals under federal juris-

diction.[95] The significance of the lack of a solid data base cannot be underestimated. The very process of risk assessment depends upon the availability of exposure data for the substance being regulated. Without that data, establishment of acceptable levels of risk and measurement of the benefits of various risk reduction techniques is difficult, at best. In view of this, the results of a recent National Research Council study on toxicity testing and exposure information indicating a paucity of data are particularly alarming.[96]

Proponents of centralization, in the form of a Science Court or Central Board, understand that these approaches cannot solve the problem of an inadequate data base. But they argue that the problems of policy decisions tainted by value judgments and lack of coordination are equally important. However, a centralized risk assessment entity, whether in the form of a Science Court or as a Board of the National Academy, would fail to address these concerns, and would create new issues.

Value-Laden Decisions

Science is not value-free. There are several distinct ways in which the risk assessment process implicitly includes value judgments in what appear initially to be scientific decisions. The process of risk assessment involves choices among alternative inference options.[97] These options vary in their degree of conservatism. The choice of a particular option, while appearing to be a technical choice, implicitly evidences the assessor's judgment about the competence of various elements of the experiment.

A scientist's choice among alternative inference options is not free from policy implications. In deciding whether to use data from animal tests or what significance to attach to it, a scientist may consider the species and gender of the animals used in the experiment's overall conditions and the characteristics of the results. However, the weighing of these factors may not be expressed explicitly.

The difficulty of separating fact-finding from value judgment, therefore, is inherent in the risk assessment process. Even a process

95. As noted *supra* in footnote 49, by most calculations, there are some five million known chemicals. Of these, about 53,500 distinct substances are regulated by the EPA and the FDA.

96. According to the NRC study, no toxicity information exists for nearly 80% of the chemicals used in commercial products and processes — substances listed in the Toxic Substances Control Act inventory. Minimal toxicity information exists for the remaining 20%. The news is only slightly better for pesticides (complete health hazard assessments are possible for about 10%). *See Toxicity Testing: Strategies to Determine Needs and Priorities*, Steering Committee on Identification of Toxic and Potentially Toxic Chemicals for Consideration by the National Toxicology Program, Board on Toxicology and Environmental Health Hazards, National Academy Press (March 1984).

97. An inference option is one of a number of choices for inferring human risk from data.

that appears to separate fact-finding from policy judgments will not change the pervasiveness of value choices within the process of fact-finding.

There are other problems with the Science Court and Central Board concepts of separating facts from values.[98] Substance control laws are based more on risks from use, production, transportation, and disposal than the regulation of substances *per se*. Consequently, the risk design of regulatory options is intimately related to the risk assessment process. Indeed, the risk assessment process involves assessing hazards and the varying levels of risk created by different regulatory options. In this framework, the design of the best option depends on continual cooperation between risk assessors and experts on regulatory design and administration.

Coordination Issues

Another argument advanced for the creation of a Science Court and Central Board is the lack of coordination that characterizes the current risk management framework. Critics suggest that the regulatory agencies have reached inconsistent results in evaluating and regulating various substances. Those inconsistent results, it is argued, lead to disparate treatment of the same chemical.[99]

In the majority of cases, the inconsistencies are the result of differing statutory, regulatory, or administrative requirements. The proposals for removing fact-finding from the agencies, and returning to them fact-finding results for policy decisions, would not change the differing statutory, regulatory, and administrative requirements.

In fact, the Science Court and Central Board concepts create more problems than they solve. Many of the problems with these proposals are process problems.[100] First, in terms of public participa-

98. Other criticisms of the separation of facts and values include: (1) the notion that such separation would artificially elevate the importance of facts over the more fundamental policy questions involved; and (2) the notion that in reality, experts don't disagree about objectively verifiable facts, as much as the inferences to be drawn from these facts.

If the latter assertion is correct, it is an argument for the uniform guideline approach, as opposed to centralization of fact-finding. *See* Talbott, *"Science Court" A Possible Way to Obtain Scientific Certainty for Decisions Based on Scientific Fact*, 8 ENVTL. L. 827 (1978); Sofaer, *The Science Court: Unscientific and Unsound*, 9 ENVTL. L. 1 (1978); Banks, *The Science Court Proposal in Retrospect: A Literature Review and Case Study*, 10 CRITICAL REVIEWS ENVTL. CONTROL 95 (1980).

99. *See supra* text accompanying notes 81-84.

100. *See* Talbott, *"Science Court" A Possible Way to Obtain Scientific Certainty for Decisions Based on Scientific Fact*. 8 ENVTL. L. 827 (1978); Martin, *Procedures for Decisionmaking Under Conditions of Scientific Certainty: The Science Court Proposal*,

tion, it is unclear how either proposal would enhance the ability of the public to participate in, be privy to, and influence decision-making. The current process, with some important exceptions, subjects agencies to the Freedom of Information Act (FOIA).[101] Agency committees, including science advisory panels, are subject to the access requirements of the Federal Advisory Committee Act (FACA).[102] However, the FACA would not apply to the Central Board under current precedent.[103] Although the Central Board proposal speaks of input from "public scientific groups,"[104] it is unclear how such input would be used. Would dissenting input be considered and/or published as part of the record? To what extent would dissenting input be invited?

Second, the Central Board proposal fails to address the role of minority or dissenting opinions among Board members. It is not clear whether a final review of an agency risk assessment would include differing opinions among Board members, or whether the impetus would be for a consensus opinion. Supposing a dissent was based on a belief that further research was needed, it is not specified how the Board or the agency would handle that recommendation.

Third, the failure of either proposal to provide for reconsideration or judicial review is also troublesome. The Central Board proposal leaves some doubt as to whether the Board plays an appellate or *de novo* role in reviewing the agency's risk assessment. The distinction between doing and *reviewing* risk assessments becomes blurred when a sense of urgency to reach conclusions exists. Creation of the Board for an appellate function will only delay decision-making.

Fourth, the Central Board proposal fails to address the possibility an agency may decide *not* to act. If the proposal is motivated by concerns for consistency of decision-making and use of the best science free of result-oriented judgments, then a decision not to act should be referrable to the Central Board as well. The legislation fails to address this likely possibility. It therefore leaves unanswered the question of standing to ask for referral resulting from agency non-action.

Finally, critics of a centralized decision-making entity have raised

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16 HARV. J. ON LEGIS. 443 (1979); Matheny & Williams, *Scientific Disputes and Adversary Procedures in Policymaking: An Evaluation of the Science Court*. 3 LAW & POL'Y Q. 341 (1981); Sofaer, *The Science Court: Unscientific and Unsound*, 9 ENVTL. L. 1 (1978); Proceedings of the Colloquium on the Science Court (Prepared for AAAS (January 1977) NTIS Doc. PB 261305).

101. 5 U.S.C. § 552 (1980).

102. 5 U.S.C. app. 10(b) (1980).

103. Lombardo v. Handler, 397 F. Supp. 792 (D.D.C. 1975), *aff'd*, 546 F.2d 1043 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 932 (1977).

104. H.R. 4192 Sec. 205(c).

concerns about the likely impact of the decisions from that body.[105] Even if decisions of the Central Board or Science Court are not binding, the implicit authority of such a body would create powerful presumptions in favor of its findings.[106] Moreover, it is suggested that the findings of such an entity could be a powerful influence in determining research directions and funding priorities.[107]

ALTERNATIVE APPROACHES FOR THE EIGHTIES

Advocates of a centralized decision-making entity suggest that the current regulatory framework for managing risk is fatally flawed; that the only possible means of correcting and improving the system is by radically altering it. But it is possible that changes within the existing system would be a more realistic and ultimately efficacious means of improving agency decision-making. Critics of the system may be insensitive to existing institutional realities, and oblivious to the fact that many of their aims are already accomplished under conventional hard-look doctrine in judicial review,[108] and could be accomplished through other, less extreme, changes.

Much of the dissatisfaction with risk assessment stems from dissatisfaction with the regulatory outcome. The centralization proposals are based on the unwarranted assumption that change in regulatory process of risk assessment would lead to more pleasing

105. *See* Talbott, *"Science Court" A Possible Way to Obtain Scientific Certainty for Decisions Based on Scientific Fact*, 8 ENVTL. L. 827 (1978); Martin, *Procedures for Decisionmaking Under Conditions of Scientific Certainty: The Science Court Proposal*, 16 HARV. J. ON LEGIS. 443 (1979); Matheny & Williams, *Scientific Disputes and Adversary Procedures in Policymaking: An Evaluation of the Science Court*, 3 LAW & POL'Y Q. 341 (1981); Sofaer, *The Science Court: Unscientific and Unsound*, 9 ENVTL. L. 1 (1978); Proceedings of the Colloquium on the Science Court, (prepared for AAAS (January 1977) NTIS Doc. PB 261305).

106. *See* Martin, *Proposed "Science Court,"* 75 MICH. L. REV. 1058 (1977); Banks, *The Science Court Proposal in Retrospect: A Literature Review and Case Study*, 10 CRITICAL REVIEWS ENVTL. CONTROL 95 (1980).

107. *Id.*

108. Without any change at all, judicial review also provides a means of scrutinizing agency decisionmaking, and ensuring that agency action is within the bounds of the statute. The dominant trend in review of regulatory decisionmaking is the "hard-look" doctrine. The key aspect of the hard-look doctrine is a requirement for reasoned agency decisionmaking. Agencies are asked to describe their methodology, sources of authority, value judgments, discarded alternatives, analysis, and the use of analysis in decisionmaking. By taking a hard-look at methodology, possibly mitigated by recognition of the limits of available knowledge, judicial review appears to be an underrated means of monitoring agency action.

See Rodgers, *Benefits Costs and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENVTL. L. REV. 191 (1980); Rodgers, *A Hard Look at Vermont Yankee: Environmental Law Under Close Scrutiny*, 67 GEO. L. J. 699 (1979).

regulatory outcomes. But the most important step may be to recognize that science in general, and the risk assessment process in particular, are *not* value-free. The critical issue is then to ensure that the agency process provides opportunities for all interested parties to present their views and that the agency's value judgments be made in a visible, reportable, and documented manner.

In addition to recognition of the role of judicial review, several other suggestions for change may be worthy of consideration. Some observers, working with the current process, have suggested ways of making science advisory committees and congressional input more meaningful.[109] In the current process, scientific peer review occurs after regulatory review and the design of options. The peer review process could be used at the fact-finding stage of agency action. After the agency has determined its regulatory priorities, the science panel might make recommendations for needed research. The agency would develop plans for such research, and the science panels would review research proposals and the overall research plan. Upon completion of fact-finding, the panel could examine the data, or the staff review of the data.

Throughout this process, current concerns about the role and power of science advisory committees might be addressed. This could be accomplished by specific task definition, a requirement to disclose in detail the specific basis on which scientific facts are determined, and the choice of inference options.

Mediation techniques could be incorporated for the presentation and discussion of scientific evidence within science advisory panels. Mediation might be as formal as the presentation of specific differing viewpoints within the committee, and the preparation of a report detailing these positions, the remaining differences, and areas of consensus.

To ensure the public accountability and openness of the process, current exceptions to the Federal Advisory Committee Act[110] could be reconsidered. FACA generally requires advisory committee meetings be conducted in public. An exception is provided for institutional advisory committees, under contract, to supply advice to the government.[111] NAS/NRC falls squarely within this exception, and its committees need not operate under FACA strictures. Yet NAS/NRC is the preeminent source of advice to the agencies. A second exception provides for science advisory committees, restricted to providing decision-makers with scientific facts, not policy recommenda-

109. *See* Martin, *Procedures for Decisionmaking Under Conditions of Scientific Certainty: The Science Court Proposal*, 16 HARV. J. ON LEGIS. 443 (1979).

110. 5 U.S.C. app. § 1 *et seq.* (1980).

111. *See* 5 U.S.C. app. 1 § 10 (1980); Lombardo v. Handler, 397 F. Supp. 792 (D.D.C. 1975), *aff'd*, 546 F.2d 1043 (D.C. Cir. 1976) *cert. denied*, 431 U.S. 932 (1977).

tions.[112] To assure public access to deliberation of scientific issues of interest, the Congress could amend FACA to repeal these exceptions.

While these proposals arguably might strengthen use of science advisory committees, other useful proposals for change are directed at the risk assessment process itself. In December 1980, Congress appropriated $500,000 to the NAS/NRC to study the institutional means for risk assessment. In February 1983, the Committee on Institutional Means for Assessment of Risks to Public Health of the NAS/NRC issued its report.[113] The report assessed the merits of separating the analytic functions of developing risk assessments from the regulatory functions of policymaking; the feasibility of centralization; and the feasibility of developing uniform risk assessment guidelines for use by all regulatory agencies.

The Committee report concluded the most fundamental problem in risk assessment was the lack of available data. Proposals for separation and centralization would not improve the knowledge base, nor lead to the design of better regulatory options. The Committee recommended a three-part program: 1) implementation of procedural changes to ensure individual assessments routinely take full advantage of the available scientific knowledge, while preserving the diversified approaches to the administration of risk assessment necessary to accommodate the varied needs of federal regulatory programs; 2) standardization of analytic procedures among federal programs through the development and use of uniform inference guidelines; and 3) creation of a mechanism that will ensure orderly and continuing review and modification of risk assessment procedures as the scientific knowledge base expands.[114]

The recommended mechanism was a board of scientists within the NAS/NRC. Their primary task, as envisioned by the Committee, would be to develop uniform inference guidelines. The Board would have no role in reviewing or performing specific risk assessments.

The Committee believed that greater use of guidelines could help to separate fact-finding from value judgments without artificially bisecting the process. Proponents of uniform guidelines also suggest that their use would ensure that risk assessors apply judgments in accord with the current scientific thinking in all the relevant fields, and ensure consistency and predictability in risk assessments and

112. *Id.*
113. *Risk Assessment in the Federal Government, supra* note 6.
114. Considered and rejected by the NAS Committee. *Id.*

risk management. The Committee believed the use of guidelines would ease pressures on strained agency resources, by reducing repetitious review in specific cases.

The notion of uniform inference guidelines, while intriguing, has problems of its own, as the NAS/NRC report itself noted.[115] First, adoption of a generic approach to chemicals, while creating consistency and predictability may preclude consideration of distinctions among substances. Blind adherence to guidelines might result in the rejection of scientific information that was not easily accommodated in the guideline approach.

Second, it is inevitable that the design and choice of inference guidelines has policy content. Guidelines would embody both scientific knowledge and policy, by establishing policy for such factors as dose-response curve and importance of negative findings. Thus, establishment of uniform guidelines will not separate fact-finding from policy content. It will, in fact, legitimate and expose it to public scrutiny.

Third, it may not be possible to adopt uniform inference guidelines for all suspect carcinogens. As current findings suggest, different substances cause cancer by different routes requiring different models.

Finally, uniform guidelines, once adopted, may prove difficult to modify. Some critics of guidelines believe they would freeze scientific evidence at a particular moment. Institutional caution and inertia would make guidelines hard to change. It is also unclear what effect such change might have on prior regulatory decisions based on risk assessments under the old guidelines.

While these problems are not significant, the uniform guideline approach is clearly in favor, judging by its past use by the IRLG, and its presence as a goal of the new, EPA-initiated interagency project. Indeed, the current House bill on risk assessment, H.R. 4192, includes a role for its Central Board in developing "Scientific criteria." However, in H.R. 4192, the potential role of scientific criteria appears to be to remove policy discretion from the agencies. In H.R. 4192, agencies are required to explain any variation from the criteria recommended by the Central Board, thus precluding their use of different options for reasons of policy.

An alternative to specification by NAS/NRC Board of uniform inference guidelines is worthy of consideration.[116] Instead of requiring the Board to develop guidelines, a more flexible approach would be to develop a list of specific issues to be addressed by risk assessment. The Board would not specify the choice of extrapolation

115. *Id.* at p. 68.
116. *Id.*

model, only that a model must be chosen, and the choice described and justified. The agencies could set inference options applicable to both the nature of the substances for which they have jurisdiction, as well as to the legislative policy by which the particular agency is guided.

From an agency point of view, even this approach may be less desirable than the process already underway. Rather than creating a Board within the NAS/NRC, a preferable approach would be the use of standing interagency committees, such as the format of the IRLG, or the current EPA-led effort. The committee, made up of the relevant agency heads or their designees, could serve to: 1) develop uniform inference choices; 2) provide a forum for airing important issues as they arise; and 3) develop a coordinated research strategy. If legislatively mandated, such an interagency committee could be established outside of the auspices of any politically-charged entity such as OSTP. By standing on its own, the committee might have a better chance of enduring different administrations, which would be critical to its ability to implement long-term goals.

CONCLUSION

The regulatory process will continue to be the subject of discussion and the focus of proposals for change. Current proposals for change focus on the risk assessment process. These proposals, reflecting older ideas about the desirability of centralizing scientific fact-finding, would remove some agency responsibility for fact-finding, and place that responsibility in a single entity. These proposals fail to recognize that their goals of separating fact-finding from value judgments and ensuring consistency, will not be reached by centralizing risk assessment in a single entity. Centralization would lead to difficult issues of input and review, and an interruption of the critical interplay between fact-finders and designers of regulatory options. Centralization would not ultimately remove the value aspect of risk assessments inherent in the choice of inference options, or insure the consistency which differing statutory mandates will always preclude.

Calls for reform of our existing system, particularly of the role of science advisory committees, are worthy of consideration. These are less dramatic and eye-catching but more attuned to the political realities of a pluralistic system. Suggestions for development of uniform inference guidelines or lists of the characteristics of a thorough risk assessment are worthy of consideration. They reflect what is already quietly occurring, through agency-initiated efforts at coordina-

tion. Finally, while judicial review is necessarily limited, the hard-look doctrine continues to provide a means of requiring reasoned and articulated agency decision-making, and should not be overlooked in the debate.