Yale Journal on Regulation
Winter, 1988

*89 GOOD SCIENCE, BAD REGULATION, AND TOXIC RISK ASSESSMENT

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Three interconnected themes . . . support the Article's central thesis that explicit social policy choices should influence agency selections of risk-assessment principles and specific risk estimates:

Inadequate scientific knowledge and inadequate data usually prevent derivation of risk estimates based on reliable science. Toxic risk assessment suffers from fundamental uncertainties about causal mechanisms for cancer and other hazards, extrapolative relationships between high-dose and low-dose responses and between animal test data and human risks, latent effects and latency periods, special sensitivities in exposed subpopulations, synergistic or co-carcinogenic effects of various substances, past and present exposure levels, dispersion patterns for contaminants, and virtually every other area of required knowledge. [FN5] These uncertainties generally preclude reliable assessments of relevant effects, and there is no scientific consensus on how they should be resolved. For example, conflicting risk estimates submitted in Food and Drug Administration (FDA) proceedings on saccharine varied by more than a millionfold; [FN6] and predictions ***92** of the hazards posed by TCE, a drinking-water contaminant, varied by many millions. [FN7] One discussion of TCE regulation noted that the 'estimates provide a range of uncertainty equivalent to not knowing whether one has enough money to buy a cup of coffee or pay off the national debt.' [FN8]

Under current regulatory practices, Agency scientists produce risk assessments that seldom approach the level of reliability normally expected of scientific findings; indeed, many estimates are little more than educated guesses. [FN9] Yet, the choice among competing estimates—a prediction of only a minuscule hazard or one a million times greater—can determine whether toxic exposures are characterized as 'acceptable' or 'unac-

ceptable' irrespective of any values in the risk-management process. Absent a scientific consensus on which risk-assessment principles should be applied, I contend that an agency's choice among competing risk estimates should not be exclusively a result of provisional scientific judgments. If substantial uncertainty exists about the extent of toxic hazards and the possible benefits from risk reduction, social consequences and political values must play an integral role in determining which speculative risk estimates are adopted.

There is an inherent tension between the disciplinary norms of good science and good regulation. Unlike in pure scientific research, where the proper response to uncertainty is reservation of judgment pending the development of adequate data and testable hypotheses, the risk-assessment process cannot be suspended without significant social consequences. A finding that a vital issue is currently indeterminate would be entirely consistent with the practice of good science, but 'no decision' on a possible toxic hazard inescapably is a decision that promotes interests which benefit from the regulatory status quo. [FN10] Risk assessment is not driven by the pursuit of knowledge for its own sake, the explicit goal of science, but by the need to decide whether potentially severe health hazards should be allowed to continue or whether high control costs should be imposed with potentially severe economic consequences. Thus, scientists in regulatory proceedings are expected to produce 'answers' in a timely manner even if their predictions are highly speculative. Any reluctance to relax the standards***93** of proof and certainty generally required of valid science may introduce a bias in favor of regulatory inaction.

Science aims at the dispassionate pursuit of truth. In contrast, scientists in risk-assessment proceedings frequently represent industries, labor unions, consumers, environmentalists, or agency bureaucracies with great interests at stake. These affiliations may often explicitly or unintentionally color interpretations of available evidence. [FN11] Scientists seldom base conclusions on data and experiments that cannot be reproduced, but information in regulatory hearings is routinely submitted by affected parties and frequently cannot be replicated or effectively challenged by other participants. [FN12] Scientists tend to design research studies in light of which data are available and which experiments may be feasible, whereas the critical questions in risk-assessment proceedings are usually determined by statutory or judicial requirements that need not be responsive to the state of scientific knowledge. [FN13] Budgetary and time limitations often influence the scientific research agenda, but no good scientist would feel that definitive answers must be produced irrespective of resource constraints. The opposite predisposition may be appropriate for good regulators. [FN14] These comments are not intended to call into question the com-

petence or ethics of all scientists who participate in risk assessments. Rather, the point is that the risk-assessment process is fundamentally shaped by the requirements, constraints, and adversarial climate of regulation, not by the disciplinary norms of science.

The illusion that risk assessment is a purely scientific activity reduces the visibility and political accountability of policy judgments that often ****94*** *guide regulatory decisions on toxic hazards.* A comparison of conflicting risk-assessment principles adopted by agencies under different administrations shows that regulators frequently do consider policy criteria when they select specific risk estimates. [FN15] Federal agencies have recently employed controversial risk-assessment assumptions to justify inaction on some hazardous substances. Regulators have also attempted to make determinations based on 'good science' without considering the implications of this approach for decisionmaking costs, regulatory delays, and opportunities for obstructive or strategic behavior by affected parties. Risk assessors often respond to scientific uncertainties by adopting conservative safety-oriented positions on some important issues while they use best-current-scientific-guess, middle-of-the-range, methodological-convenience, or least-cost treatments on other material issues. EPA and other agencies have never explained the scientific or policy rationales underlying these inconsistent treatments of uncertainty, and risk managers may not recognize that substantial inconsistency exists. In light of these diverse risk-assessment practices, I contend that regulatory policy judgments as well as scientific judgments must be applied coherently, explained forthrightly, and tested actively through public debate.

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[FN5]. For example, William Ruckelshaus, then Administrator of EPA, observed:

> In assessing a suspected carcinogen . . . there are uncertainties at every point where an assumption must be made: in calculating exposure, in extrapolating from high doses where we have seen an effect to the low doses typical of environmental pollution; in what we may expect when humans are subjected to much lower doses of a substance that, when given in high doses, caused tumors in laboratory animals; and finally, in the very mechanisms by which we suppose the disease to work.

Ruckelshaus, *Science, Risk, and Public Policy*, 221 SCIENCE 1026, 1027 (1983). For policy-oriented discussions of the effects of scientific and medical uncertainties on toxic substances regulation, see NATIONAL RESEARCH COUNCIL, DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY (1977) [hereinafter EPA DECISION MAKING]; Latin, *The 'Significance' of Toxic Health Risks: An Essay on Legal Decisionmaking Under Uncertainty*, 10 ECOLOGY L.Q. 339 (1982); McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729 (1979).

[FN6]. *See* OSHA, Identification, Classification and Regulation of Potential Occupational Carcinogens, 45 Fed. Reg. 5002, 5200 (1980) (codified at 29 C.F.R. §§ 1900.101-1990.152 (1987)) [hereinafter OSHA Generic Cancer Policy]; Leape, *Quantitative Risk Assessment in Regulation of Environmental Carcinogens*, 4 HARV. ENVTL. L. REV. 86, 103 (1980).

[FN7]. *See* Cothern, Coniglio & Marcus, *Estimating Risk to Human Health*, 20 ENVTL. SCI. & TECH. 111, 113-15 (1986).

[FN8]. *Id.* at 115.

[FN9]. These speculative estimates are often presented in misleadingly precise quantitative terms. *See infra* text accompanying notes 91-144, 174-84.

[FN10]. *See* Bazelon, *Science and Uncertainty: A Jurist's View*, 5 HARV. ENVTL. L. REV. 209, 213 (1981); Latin, *supra* note 5, at 339.

[FN11]. For discussions of how conflicting private and bureaucratic incentives may impede effective environmental regulation, see Latin, *Ideal Versus Real Regulatory Efficiency: Implementation of Uniform Standards and 'Fine-Tuning' Regulatory Reforms*, 37 STAN. L. REV. 1267, 1282-97 (1985); Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 CALIF. L. REV. 1256, 1274-75, 1338-53 (1981).

Scientists are no more immune to cognitive dissonance and wishful thinking than are nonscientists.

[FN12]. For example, agencies are largely dependent on polluting industries for information on current discharge levels and on the cost/profitability criteria needed to assess whether proposed standards would be economically feasible. *See* EPA Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, and Benzene Storage Vessels; Proposed Withdrawal of Proposed Standards, 49 Fed. Reg. 8386, 8389 (1984); Latin, *The Feasibility of Occupational Health Standardss: An Essay on Legal Decisionmaking Under Uncertainty*, 78 NW. U.L. REV. 583, 605-11 (1983).

[FN13]. For examples of cases in which reviewing courts required quantitative risk assessments based on their interpretation of statutory provisions, without regard to whether the agencies were able to produce reliable risk estimates given the level of available data and scientific knowledge, see Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980); Gulf S. Insulation v. Consumer Prod. Safety Comm'n, 701 F.2d 1137 (5th Cir. 1983); Texas Indep. Ginners Ass'n v. Marshall, 630 F.2d 398 (5th Cir. 1980).

[FN14]. When harm will be substantially irreversible, as in the cases of carcinogenic exposures, extinction of species, or acid-rain contamination of lakes and forests, the problem of how long regulators should wait for ‘enough’ information to enable reliable scientific judgments is likely to be controversial. *See* Latin, *supra* note 11, at 1282-83 & n.78; Latin, *supra* note 5, at 384-85.

[FN15]. *See infra* text accompanying notes 44-52, 62-69, 198-202.