William D. Ruckleshaus served as EPA's first administrator, then was "reincarnated as Administrator of EPA" in the 1980s (see pp. 198–199). Courtesy of the Environmental Protection Agency Office of Public Affairs.

Science, Politics, and the Renegotiation of Expertise at EPA

*By Sheila Jasanoff**

SCIENCE IN THE POSTWAR ERA has acquired all the conventional trappings of "bigness"—mammoth facilities, complex technological systems, large research teams, long-running projects.[1] But in America that bigness can no longer be measured solely in terms of such tangible properties. It is as much or more a function of the social consequences of science, reflected both in the costs of doing research and in the impact of scientific findings on public decisions. The success story of government funding, often recounted in the annals of postwar science, tells how the nation recognized and rewarded the wartime contributions of science and technology by committing substantial resources to research and development. Driven by an optimistic consensus about the instrumental uses of science, federal support for research grew by as much as 14 percent annually from 1953 to 1961, before new limits were set in the skeptical mood of the Vietnam era.[2] Less noticeably perhaps, scientific research in the 1970s began laying the foundation for public policies of enormous economic impact. The trend was especially notable in the area of environmental regulation, where science and technology provided the rationale for imposing unprecedented burdens on industry. In 1988, for example, the cost of all federal policies on air pollution control was estimated to be about $30 billion; estimates of the current direct costs of compliance with U.S. pollution control laws are in the range of $100–$115 billion a year.[3]

Science during this period became not only big but also public as never before. There were numerous reasons for this new visibility. As the federal investment in science increased, the American public demanded a more active role in determining how its tax dollars should be spent. Political oversight of both funding and research organizations became routine, resulting at times in such dramatic con-

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[1] Derek J. DeSolla Price, *Little Science, Big Science . . . and Beyond* (New York: Columbia Univ. Press, 1986).

[2] Bruce L. R. Smith, *American Science Policy Since World War II* (Washington, D.C.: Brookings Institution, 1990). See also the article by Roger L. Geiger in this volume.

[3] A. Myrick Freeman III, "Economics, Incentives, and Environmental Regulation," in *Environmental Policy in the 1990s,* ed. Norman J. Vig and Michael E. Kraft (Washington, D.C.: Congressional Quarterly Press, 1990), pp. 151–152; and *Toward Common Measures* (Washington, D.C.: Federal Focus, 1991), p. 8 (estimates based on reports by the Environmental Protection Agency and the Council of Economic Advisers).

frontations as Senator William Proxmire's "golden fleece awards" for wasteful research in the 1970s and, more recently, Representative John Dingell's aggressive inquiries into scientific misconduct and indirect cost charges by universities.[4] Scientists' own stakes in making their work public expanded in tandem with the growing commercial potential of research. By the 1980s science and the media were joined in a sometimes unholy alliance of mutual aggrandizement, reaching a crescendo in 1989 with the unbridled press coverage of the "discovery" of cold fusion.[5]

These developments signaled the emergence of a "Public Science of press conferences, television, Nobel Prize races, best-sellers, and Congressional testimony."[6] Concurrently, however, there emerged a less heroic brand of public science with equally important implications for the nation's welfare: scientific research and analysis carried out for such public purposes as the regulation of risks to health, safety, and the environment.[7] A prime locus for the conduct of such research after 1970 was the newly established Environmental Protection Agency (EPA), whose scientific activities were linked to an ever more diversified portfolio of pollution control and product approval programs.

The divergent pathways by which American science went public in the last decades of the twentieth century point to an essential paradox in people's expectations from this powerful social institution. On the one hand, heightened scientific activity within government and rising demand by policymakers for "good science" were apparently premised on confidence that scientific information had the power to legitimate societal decisions entailing significant economic and political costs. On the other hand, the theater of congressional inquiries and investigative journalism gave expression to a profound public alienation from science and a loss of faith in its ability "to speak truth to power."[8] My aim in this article is to trace the impact of these contradictory influences on the production and use of science at the EPA. How has this perennially embattled agency balanced the need for scientific credibility with persistent and skeptical scrutiny of its research and

[4] Initiated in 1975, Proxmire's awards continued monthly until his retirement from politics at the end of the 100th Congress in 1988. Similar discontent with research spending by the National Science Foundation led the House of Representatives in 1975 to approve a measure that would have required Congress to screen 14,000 awards annually: see Smith, *American Science Policy* (cit. n. 2), pp. 75–76. On Dingell see David P. Hamilton, "Verdict in Sight in the 'Baltimore Case,' " *Science,* 1991 *251:* 1168–1172; Hamilton, "Stanford in the Hot Seat," *ibid.,* p. 1420; and Hamilton, "NIH Takes Heat for Lax Investigation," *ibid.,* p. 1305.

[5] Nicholas Wade, *The Science Business* (Report of the Twentieth Century Fund Task Force on the Commercialization of Research) (New York: Priority Press, 1984); and Frank Close, *Too Hot to Handle* (Princeton, N.J.: Princeton Univ. Press, 1990). See also the article by Bruce Lewenstein in this volume. For a more general account of the collaboration between science and the press see Dorothy Nelkin, *Selling Science: How the Press Covers Science and Technology* (New York: W. H. Freeman, 1987).

[6] Daryl E. Chubin and Edward J. Hackett, *Peerless Science: Peer Review and U.S. Science Policy* (Albany, N.Y.: SUNY Press, 1990), pp. 129–130.

[7] Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, Mass.: Harvard Univ. Press, 1990), pp. 40–43.

[8] This has become a favorite metaphor for the idealized relationship between scientists and policymakers. See "The Spectrum from Truth to Power," Ch. 5 in Don K. Price, *The Scientific Estate* (Cambridge, Mass.: Harvard Univ. Press, 1965); Aaron Wildavsky, *Speaking Truth to Power: The Art and Craft of Policy Analysis* (Boston: Little, Brown, 1979); "Mixing Truth with Power," Ch. 8 in Mark E. Rushefsky, *Making Cancer Policy* (Albany, N.Y.: SUNY Press, 1986); and David Collingridge and Colin Reeve, *Science Speaks to Power* (London: Pinter, 1986).

risk assessment activities? What are the salient features of the science that EPA has mustered to support its policy conclusions? What lessons, in turn, do EPA's experiences hold for our understanding of the nature of postwar science and its relation to political authority?

Since the beginning of the Scientific Revolution, science has been represented, on the whole successfully, as a body of knowledge about nature whose truth can be established through public tests, publicly witnessed.[9] Yaron Ezrahi has argued that the capacity of science to be witnessed served as a powerful resource for modern liberal democratic politics, allowing political actors to represent their actions as testable and transparent, like scientific experiments.[10] I will try to show that in the arena of environmental decision making the public representation of science has shifted away from an emphasis on testable knowledge claims to a preoccupation with the processes of knowledge production. Under continual assault from political adversaries, EPA's environmental science has more and more justified itself in terms of its legal, institutional, and procedural underpinnings rather than the truth-value of the facts it alleges. This legitimation strategy, however, has created an almost intolerable dissonance between the actual practice of policy-relevant science, which tends to assimilate science to politics, and the public's continuing demand for decisions based on politically untainted knowledge. How Congress, EPA, and various interest groups have responded to this challenge—largely by renegotiating the basis for EPA's claims to expert authority—forms the second major theme of this essay.

A rounded account of science in relation to environmental policy requires forays into several types of literature that remain all too frequently unconnected. Yet such disciplinary boundary crossing is increasingly a prerequisite for trying to understand how science in the later twentieth century fits into its social context. Thus my examples of EPA's scientific practice in this article are based on records of legislative, administrative, and judicial decision making, but they are embedded in a matrix of theoretical work in political and policy analysis and social studies of science. In this respect the article may serve as a modest exemplar of the way to study "science after '40," particularly in its interactions with public policy.

I. THE PERILS OF PREDICTION

The early 1970s saw a rapid transformation in the nature of the scientific tasks confronting EPA. The youthful agency was established by a presidential reorganization plan whose main purpose was to consolidate the federal government's pollution control activities within a single administrative unit. President Nixon's message accompanying the plan unambiguously linked EPA's role to the concept of pollution. The agency was to protect the environment "by abating pollution" and to "focus on setting and enforcing pollution control standards." It was to conduct research "on the adverse effects of pollution and on methods and equipment for controlling it," to gather information on pollution, and to use this information

[9] See, e.g., the account of Robert Boyle's experimental and rhetorical strategies for the production of facts in Steven Shapin and Simon Schaffer, *Leviathan and the Air-Pump: Hobbes, Boyle, and the Experimental Life* (Princeton, N.J.: Princeton Univ. Press, 1985). See also Donna Haraway, *Primate Visions* (London: Routledge, 1989), pp. 4–5.

[10] Yaron Ezrahi, *The Descent of Icarus* (Cambridge, Mass.: Harvard Univ. Press, 1990), pp. 66–96.

in setting environmental protection goals."[11] This delineation of EPA's agenda reflected an understanding of environmental problems that was as pragmatic as it was shortsighted. As far as the White House was concerned, the harms that the new agency was asked to redress were real and observable, capable of abatement, not speculative or lying in some dim and indiscernible future.

But even while EPA was being pieced together from existing agencies by an act of bionic bureaucracy-making, Congress was busy articulating a more ambitious set of environmental objectives than those conceived by the White House strategists. The regulatory programs enacted by Congress from 1969 onwards attached as much importance to preventing future harm as to controlling past damage. Risk, or the possibility of adverse effects, displaced pollution as the watchword of the new regulatory era. This movement was already perceptible in the 1969 National Environmental Policy Act, which required federal agencies to assess the likely environmental impact of their major proposed actions.[12] The notion of risk-driven regulation was further consolidated in rapidly succeeding statutes, including the 1970 Clean Air Act's injunction to protect public health with "an ample of margin of safety," the 1972 pesticide law's mandate to prevent "unreasonable adverse effects" on the environment, and the 1976 Toxic Substance Control Act's commandment to regulate substances presenting "an unreasonable risk of injury to health or the environment."[13]

If there were any ambiguities about how these statutes would be construed in practice, the federal courts hastened to dispel them in ways that expanded EPA's freedom to act. Thus, in a landmark case decided in 1976 under the Clean Air Act, the Court of Appeals for the D.C. Circuit concluded that certainty of harm was not a prerequisite for regulation. EPA could restrict industrial activity even on the basis of imperfect knowledge; agencies, the court declared, "are not limited to scientific fact, to 95% certainties." Similarly, in a decision interpreting EPA's obligations with respect to pesticides, the same court upheld the administrator's judgment that he could regulate a substance based on substantial, though not conclusive, evidence of its carcinogenicity.[14]

Inside the agency, too, thinking about environmental hazards was transformed within a decade. William Ruckelshaus, EPA's first administrator, whom President Reagan brought back to fill that office after the disasters of Anne Gorsuch's administration, was as well positioned as anyone in Washington to comment on the agency's changing self-perception. Recalling his early optimism about environmental regulation, Ruckelshaus ruefully observed in a speech to the National Academy of Sciences, "Perhaps God is repaying me for my error by causing me to be reincarnated as Administrator of EPA." Ruckelshaus noted that the agency he inherited in the 1980s was a different place from the EPA that he had helped to

[11] Message of the President Relative to Reorganization Plans Nos. 3 and 4 of 1970, 9 July 1970; reproduced as Appendix H in *Environmental Quality* (The First Annual Report of the Council on Environmental Quality) (Washington, D.C.: Government Printing Office [GPO], 1970), p. 300.

[12] Public Law 91-190 (1 Jan. 1970), Sec. 102.

[13] For a useful summary of risk control provisions in federal law, see Table I-2, "Public Laws Providing for the Regulation of Exposure to Carcinogens," in National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (Washington, D.C.: National Academy Press, 1983), pp. 44–47.

[14] *Ethyl Corp. v. EPA, Federal Reporter*, 2nd series, *541*(1):28 (D.C. Cir. 1976), quoting from note 58; and *Environmental Defense Fund v. EPA, Fed. Rep.*, 2nd ser., *548*:998 (D.C. Cir. 1977).

launch in the early 1970s. The agency in its second decade was trying to deal with hundreds of pollutants that were widespread, detectable at minute concentrations, and with no scientifically determinable safe levels of exposure. Given the nature of these hazards, EPA could no longer tell the public "you are home free with an adequate margin of safety."[15]

The confluence of congressional and judicial mandates, pressure from environmental groups, and its own sense of mission led EPA by the end of the 1970s increasingly into grey areas of scientific inquiry. Not only were the effects that the agency sought to prevent largely hypothetical, but the methods by which it tried to demonstrate risk were novel, untested, and frequently controversial. The attempt to set standards or regulate products based on such exercises understandably gave rise to disputes over the adequacy of EPA's scientific record. EPA was called to account for its use of science by Congress, the courts, the Executive Office of the President, and its own scientific advisers. These confrontations provide a synoptic view of the attacks on EPA's expertise and the strategies it evolved to combat them.

Some of the most persistent criticism arose in connection with EPA's efforts to measure the effects of low-dose exposures to pollutants that were known to be injurious at higher exposure levels. Clinical and epidemiological studies that looked directly at the effects of pollution on human populations were rife with problems. EPA was faulted for using inadequately validated protocols, omitting proper controls, and failing to seek competent scientific peer review.[16] In other cases experts questioned whether EPA's definition of "adverse health effects" was consistent with prevailing medical opinion.[17] Studies involving laboratory animals proved, if anything, to be even more problematic. The agency came under fire for overlooking inadequacies in the design and conduct of animal studies as well as in the principles it used to extract estimates of risk to humans from such data.[18] Claims that policy biases had distorted the agency's scientific judgment lent added fuel to the charges of chronic technical incompetence.[19]

The controversies that began to overwhelm EPA by the late 1970s involved in some instances the most basic principles of doing science. Why had an EPA consultant failed to use contemporaneous controls in an epidemiological study and

[15] William D. Ruckelshaus, "Science, Risk and Public Policy," *Ecolibrium,* 1983, *12*:16–18, on pp. 16, 17.

[16] See, e.g., the cases described in Jasanoff, *The Fifth Branch,* (cit. n. 7), pp. 21–32.

[17] *Ibid.,* p. 108. See also *Lead Industries Association, Inc., v. EPA, Fed. Rep.*, 2nd ser., 1980, *647*:1330 (D.C. Cir. 1980). In this case the court rejected industry's argument that only "clearly harmful" effects could be counted as "adverse" for purposes of setting standards. The court also denied that a medical consensus was needed to show that an effect was harmful.

[18] In 1980, for example, a National Research Council committee found that EPA's Office of Pesticide Programs was carrying the quantification of risk to an unwarranted extreme. The NRC report observed that "our present understanding of the mechanisms of cancer development does not permit us to draw reliable numerical inferences from the kind of laboratory data normally available about the effects of pesticides and other compounds on the development of cancers in humans." NRC, *Regulating Pesticides* (Washington, D.C.: National Academy Press, 1980), p. 6.

[19] Worries about policy bias in the interpretation of animal studies led to the 1983 NRC study of risk assessment cited in n. 13. See also William R. Havender, "EDB and the Marigold Option," *Regulation,* Jan./Feb. 1984, pp. 13–17 (accusation by a biologist that EPA was excessively conservative in its statistical model for assessing risk). For a still more recent expression of these concerns see Executive Office of the President, *Regulatory Program of the United States Government, April 1, 1990–March 31, 1991,* (Washington, D.C.: GPO, [1991]), pp. 13–26.

why had he not established a baseline measure of the presumed adverse condition (in this case chromosomal damage) in the general population?[20] Why in another study had EPA failed to show a statistically significant correlation between maternal exposure to the alleged toxicant and the posited health effect (spontaneous abortions)?[21] In other instances, however, the scientific charges against EPA centered on what lawyers could reasonably call "cases of first impression." How should EPA measure an exercising human subject's exposure to ozone or determine a rat's exposure to formaldehyde? Were scientifically acceptable methods available to measure ambient concentrations of asbestos fiber in buildings? Issues similar to these are commonplace in the practice of any experimental science, where they are normally resolved by negotiation among groups of interested researchers. In the context of environmental decision making, however, EPA frequently was required to choose among competing resolutions before consensus practices could develop and be certified as valid by an authoritative research community.

The legal framework within which EPA operates magnified the difficulty of maintaining scientific credibility. Like all U.S. administrative agencies, EPA carries out its scientific affairs in the open, with numerous opportunities for interested parties to contest its choices and decisions. The adversarial format of these encounters afforded EPA little opportunity to maintain a posture of neutrality. During rule-making proceedings, for example, the agency was often a party to an adversarial showdown before a scientific advisory committee or a court; at other times it had to align itself openly with scientific arguments advanced by environmentalists or regulated industries. In either situation it was difficult to avoid giving the impression that scientific judgment was playing second fiddle to the dictates of policy.

These defects of the adversarial approach were not self-evident when EPA first came into being. Support for this method of resolving regulatory disputes came from such influential quarters as the physicist Alvin Weinberg, who suggested in a 1972 article that the adversary procedure was "the best alternative" for "trans-scientific" questions, and Chief Judge David Bazelon of the Court of Appeals for the D.C. Circuit, who became a tireless champion for an open give-and-take on technical issues in environmental decision making.[22] Astute observers of EPA's rule-making practices, however, quickly recognized that the agency's claim to scientific objectivity was seriously threatened by adversarial exposure. A study carried out by the National Research Council (NRC) between 1974 and 1976 noted

[20] These issues arose in connection with a study of chromosomal damage at Love Canal carried out by Dante Picciano. Picciano's study was severely criticized by several authoritative peer review committees. See, e.g., Lewis Thomas *et al.*, "Report of the Governor's Panel to Review Scientific Studies and the Development of Public Policy on Problems Resulting from Hazardous Wastes," New York, N.Y., Oct. 1980. For a sociologically grounded critique of the Thomas report see Adeline Gordon Levine, *Love Canal: Science, Politics, and People,* (Lexington, Mass.: Lexington Books, 1982), pp. 157–168.

[21] This and related methodological questions were raised in connection with an EPA study of the effects of the weed-killer 2,4,5-T. See *Dow Chemical Company v. Blum, Federal Supplement, 469*:892 (E.D. Mich 1979).

[22] Alvin Weinberg, "Science and Trans-Science," *Minerva,* 1972, *10*:209–222, on p. 215; and, e.g., *Natural Resources Defense Council v. Nuclear Regulatory Commission, Fed. Rep.*, 2nd ser., *547*:633 (D.C. Cir. 1976), p. 645. See also Jasanoff, *The Fifth Branch* (cit. n. 7), p. 55. Weinberg coined *trans-science* to refer to the gray area between science and policy.

this systemic difficulty: "Much of the process by which EPA makes regulatory decisions is adversarial, and often scientific information is provided by one of the principals. Similarly, the Agency itself is sometimes placed in an advocacy role."[23] The antidote proposed by the NRC was that EPA should seek validation from scientific experts located outside the agency through the mechanism of peer review. As we shall see, this procedural recommendation was a portent of things to come.

Another difficulty that manifested itself over time was the incompatibility between adversarial procedures and the closure of scientific debates relevant to public policy. The science of environmental risk assessment was distant indeed from the cohesive, smoothly functioning assembly of claims and supporters that sociologist of science Bruno Latour terms "black boxes." Instead, EPA's risk constructs were susceptible to deconstruction in much the same way as laboratory research findings before they have begun to attract substantial alliances among scientists.[24] Under hostile scrutiny EPA's explanations for its risk determinations became more detailed and explicit, but increasing clarity did not necessarily improve the chances for ending conflict. The formulation of guidelines for cancer risk assessment, a dominant agency concern for the past twenty years, illustrates these dynamics of deconstruction and helps explain why reliance on process-based justification of risk estimates became more commonplace over this period.

II. CANCER RISK ASSESSMENT: THE ASSIMILATION OF SCIENCE TO POLITICS

Early in its existence EPA identified carcinogenic chemicals as an important regulatory target. The reasons for this choice have been rehearsed in many places and need only be summarized here. Briefly, one line of explanation holds that postwar anxieties about uncontrollable technology reinforced the American public's deep-seated fear of cancer to produce an obsessive concern with chemicals in the environment. In one of the most detailed expositions of this view, Edith Efron charged that "apocalyptic" scientists at the National Cancer Institute had captured the minds of regulators and the public with four false "axioms" concerning the causes and prevalence of cancer in the United States. Health risks, as others have noted, tend to override environmental concerns in America's collective psyche as a spur to political initiative.[25] American environmentalists, according to the anthropologist Mary Douglas and the political scientist Aaron Wildavsky, were particularly receptive to theories connecting pollution and ill health because of their sectarian organization and beliefs. Comparative policy analysts, meanwhile, pointed to the responsiveness of the U.S. political and legal system, which readily translated these national anxieties, whatever their underlying causes, into a focal point for governmental action.[26]

[23] National Research Council, *Decision Making in the Environmental Protection Agency,* Vol. II (Washington, D.C.: National Academy Press, 1977), p. 48.

[24] For "black boxes" see Bruno Latour, *Science in Action* (Cambridge, Mass.: Harvard Univ. Press, 1987), pp. 130–131; for the construction of scientific facts within the laboratory see Bruno Latour and Steve Woolgar, *Laboratory Life* (Princeton, N.J.: Princeton Univ. Press, 1986).

[25] Edith Efron, *The Apocalyptics* (New York: Simon & Schuster, 1984), pp. 426–459; and Edward J. Burger, Jr., "Health as a Surrogate for the Environment," *Daedalus,* 1990, *119*:133–153. For an influential defense of the "apocalyptic" vision see Samuel S. Epstein, *The Politics of Cancer* (Garden City, N.Y.: Anchor Press, 1979).

[26] Mary Douglas and Aaron Wildavsky, *Risk and Culture* (Berkeley/Los Angeles: Univ. California

Our primary concern here, however, is with the aftermath of political agenda setting—that is, with EPA's attempts to implement its mission to control carcinogens in a scientifically credible manner. Central to the story is a gradual shift in the agency's strategy in the 1970s, from stating a knowledge claim of regulatory significance (substance X is a carcinogen) to giving intricate explanations of the process by which it came to that factual conclusion. The agency also slipped into increasing dependence on political forms of legitimation when defending the validity of its scientific thought processes.

The shift in explanatory strategy from reliance on facts to reliance on process occurred at two distinct levels: the analytical and the institutional. As the practice and politics of regulation matured, decisions to label a substance as a carcinogen had to conform both to an explicitly articulated process of reasoning and to a process of certification by other expert institutions. The two legitimation paths were necessarily interdependent (interactions with other expert bodies influenced EPA's analytical methods, and vice versa), but I separate them here in the interests of narrative simplicity.

The motivating force for both the analytical and the institutional unpacking of EPA's carcinogenicity claims was the need to take seriously the precautionary mandate of the new environmental statutes, which as we have seen required the reduction of risk as well as the abatement of harm. In order to fulfill its protective mission, EPA had to identify and regulate suspected carcinogens before there was conclusive proof that they did indeed cause cancer in humans. The political environment of the 1970s ruled out the option of waiting until injury was manifest, as the nation had done in the case of worker deaths and injuries from asbestos.[27] Lacking definitive proof of harm (or, in Vietnam-conditioned language, a "body count"), EPA had to find other bases for establishing that a suspected cancer agent presented an "unreasonable risk" to human health. Animal studies provided by far the most compelling alternate source of evidence—there was a reasonable scientific consensus that substances producing tumors in animals would do the same in humans—but interpreting these studies proved to be anything but straightforward.

EPA soon discovered that numerous assumptions were needed to build a reliable chain of inferences from positive animal tests to the presumption of human carcinogenicity. The idea that the scientific community could agree on a set of principles for deriving conclusions about cancer risks to humans had been broached in 1970 by an ad hoc committee of scientists in a report to the Surgeon

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Press, 1982); and, among policy analysts, Brendan Gillespie, Dave Eva, and Ron Johnston, "Carcinogenic Risk Assessment in the United States and Great Britain: The Case of Aldrin/Dieldrin," *Social Studies of Science,* 1984, *14*:265–301; and Ronald Brickman, Sheila Jasanoff, and Thomas Ilgen, *Controlling Chemicals: The Politics of Regulation in Europe and the United States* (Ithaca, N.Y.: Cornell Univ. Press, 1985).

[27] The importance of the asbestos case in shaping political opinion on carcinogens was vividly apparent in the legislative debate on the Toxic Substances Control Act, Public Law 94-469 (1976). See, e.g., the remarks of Senator John V. Tunney: "I was horrified to learn that we have asbestos in many of our body powders, and that when youngsters' mothers put powder on them, this can be inhaled into their lungs and that asbestos sits in the follicles of the lung and can produce cancer 20 years later." House Committee on Interstate and Foreign Commerce, *Legislative History of the Toxic Substances Control Act* (Washington, D.C.: GPO, 1976), p. 211.

General.[28] EPA incorporated this idea into its own practice largely under pressure of litigation, as a string of pesticide manufacturers began taking the agency to court to challenge proposed restrictions on the uses of their products. What began as a simple exercise in "reasoned decision making" led to one of the most contentious science policy disputes confronting the agency.[29]

The Quest for Principles

The development of guidelines for assessing cancer risks seems in retrospect to have stood the normal process of scientific fact making on its head. The reason becomes clear if we compare EPA's objectives and strategies in risk assessment with those of ordinary working scientists who seek to translate laboratory observations into factual claims. Scientific fact builders strive, in Bruno Latour's happy metaphor, to convert their facts into "an obligatory passage point" for everyone else who wishes to pursue the same interests.[30] Facts are intended to serve as building blocks for other facts. The successful scientist makes claims that become so routine and so indispensable that no one stops to question them or to probe into the circumstances behind their making. Progress toward this goal begins as early in the process as the selection of a "literary technology"[31] that puts the individual observer in the background and makes the "facts" speak for themselves.

In the context of regulation, by contrast, scientific "facts" serve as a bridge not to other facts but to policy decisions. They undergo no subsequent testing at the hands of scientists, so that their legitimacy depends exclusively on the manner of their production. Yet they must be robust enough to underpin decisions entailing significant social costs. EPA's cancer risk assessment guidelines tried to meet these unusual demands by turning a ruthless spotlight on the hinterland of construction and conjecture lying behind each claim that substance X was a carcinogen. The presumption was that the validity of the policy-relevant fact (X's carcinogenicity) could only be established by making explicit the stages leading to its creation. Instead of putting the claim into a black box as in normal science, EPA exposed its contents, as required by the rules of political and legal legitimation; in so doing, the agency practically compelled questioning of the coherence, logic, and wisdom of its reasoning. Most especially, this strategy focused attention on the leap of inference that connected the generality of the guidelines to the specificity of the carcinogenicity finding in particular cases.

EPA first codified its approach to identifying carcinogens in 1972 in the form of seven "cancer principles" that were invoked to cancel the registration of DDT.[32]

[28] Rushefsky, *Making Cancer Policy* (cit. n. 8), pp. 75–77.

[29] Under U.S. administrative law, regulatory agencies are required to show that they have engaged in reasoned decision making. This means that "[a]ssumptions must be spelled out, inconsistencies explained, methodologies disclosed, contradictory evidence rebutted, record references solidly grounded, guesswork eliminated and conclusions supported 'in a manner capable of judicial understanding.' " William H. Rodgers, Jr., "A Hard Look at Vermont Yankee: Environmental Law under Close Scrutiny," *Georgetown Law Journal,* 1979, *67*:699–727, on p. 706.

[30] Latour, *Science in Action* (cit. n. 24), p. 132.

[31] Shapin and Schaffer, *Leviathan and the Air-Pump* (cit. n. 9), p. 25.

[32] Nathan J. Karch, "Explicit Criteria and Principles for Identifying Carcinogens: A Focus of Controversy at the Environmental Protection Agency," in National Research Council, *Decision Making in the Environmental Protection Agency,* Vol. IIA (Washington, D.C.: National Academy Press, 1977), p. 131.

Periodic revisions and refinements of these principles led to the issuance of "Interim Procedures and Guidelines for Health Risk Assessments of Suspected Carcinogens" in 1976 and "Guidelines for Carcinogen Risk Assessment" in 1986.[33] Both the content and context of these reformulations have been amply described elsewhere from a variety of disciplinary perspectives.[34] The point to note here is that the risk assessment guidelines were the formal embodiment of a process of reasoning that EPA was committing itself to follow in every decision involving carcinogens. It was the validity of this process that eventually became a major focus for legal conflicts involving EPA.

Litigation not only opened up the agency's analytical processes to critical public review but also forced EPA to account more explicitly for its assumptions and uncertainties. The deconstructive effect of the law was soon observable in the growing number and complexity of the risk assessment guidelines. EPA's seven principles for DDT had risen to seventeen by the time the agency turned its attention to the pesticides heptachlor and chlordane in 1975; by 1985 the Office of Science and Technology Policy (OSTP) had articulated thirty-one general principles for cancer risk assessment, to be supplemented as needed by each regulatory agency's more specific guidelines.[35] Ironically, as the number of guidelines multiplied, their open-endedness also became more apparent. In the 1986 guidelines, for example, EPA made it clear that general principles for assessing cancer risk might have to be modified in the light of evidence about specific chemicals. Thus, although EPA adopted the linearized multistage model as the default method for extrapolating risk from high to low doses, the guidelines observed that this choice was not immutable: "When pharmacokinetic or metabolism data are available, or when other substantial evidence on the mechanistic aspects of the carcinogenesis process exists, a low-dose extrapolation model other than the linearized multistage procedure might be considered more appropriate on biological grounds."[36] EPA, in other words, was prepared to let new science override its default positions, but the decision when to deviate from the guidelines remained firmly within the agency's control.

By the early 1990s even this state of affairs had grown nearly untenable. Some of EPA's critics felt that the agency was using the guidelines to block discussion of far-reaching uncertainties about the mechanisms of cancer causation. Agency experts were accused of generating misleadingly precise estimates of risk by failing to display the range of uncertainty associated with each of their assumptions. A study done at Resources for the Future, a Washington-based policy institute, recommended a method for overcoming this problem and received favorable cover-

[33] *Federal Register,* 1976, *41*:21402–21405; and *ibid.*, 1986, *51*:33992–34003.

[34] Rushefsky traces these developments from a political scientist's point of view in *Making Cancer Policy* (cit. n. 8). For a lawyer's account of the early phases of carcinogen regulation, see Thomas O. McGarity, "Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA," *Georgetown Law Review,* 1979, *67*:729–810. For a science studies perspective on the same story see Sheila Jasanoff, "The Problem of Rationality in American Health and Safety Regulation," in *Expert Evidence: Interpreting Science in the Law,* ed. Roger Smith and Brian Wynne (London: Routledge, 1989), pp. 151–183; see also Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 181–193.

[35] Jasanoff, "The Problem of Rationality," p. 166.

[36] *Federal Register,* 1986, *51*:33998.

age in the science press.[37] Other voices from industry and the scientific community united in claiming that advancing science had invalidated some of EPA's default assumptions and that these should be modified, abandoned or extended to take account of new knowledge. Far from becoming an "obligatory passage point," the guidelines in fact had turned into obstacles that other actors strove vigorously to sidestep by advocating their own alternative formulations.

In trying to establish its command over fact building about carcinogens, EPA ironically had lost exclusive control of the process. Other agencies and interests intervened to correct what they perceived as deficiencies in EPA's approach. The chemical industry, predictably, was one of the most influential, since chemical manufacturers had the most to gain from a relaxation of EPA's default assumptions. The American Industrial Health Council, a coalition of chemical companies and trade associations, emerged as a strong and persistent critic of federal cancer policies.[38] Other critics were located within the executive branch, as EPA itself was, but were more closely identified with the deregulatory ideology of the Reagan White House. These included the Office of Management and Budget (OMB) and for a time the OSTP.[39] The scientific community, too, became a participant in the debate, represented most influentially by the National Research Council, whose committees periodically, and critically, investigated EPA's risk assessment practices. Finally, environmental, labor, and consumer groups also became involved in risk assessment, although they with few exceptions endorsed the conservative assumptions embedded in the agency's approach. In short, by the mid 1980s most of the important players on the American regulatory scene had staked out a claim to speak about the rights and wrongs of cancer risk assessment. The map of scientific positions on this single issue had come to bear an uncanny resemblance to the map of environmental politics as a whole.

Political Solutions

These developments may explain the second legitimation strategy that EPA followed with greater frequency from the late 1970s: to seek refuge in consultations with scientific experts drawn from outside the agency. It took some time for the agency to develop the practice of consultation into an effective shield against its detractors in the political arena. In its earliest efforts to validate the cancer principles, EPA underestimated the need for support from outside the government. Agency officials initially turned to Dr. Umberto Saffiotti of the National Cancer Institute to refine the principles so as to withstand challenges from the pesticide industry. Saffiotti, however, was seen as too much a partisan of regulation (Efron called him "one of the founding fathers of the contemporary crusade against industrial cancer"[40]) to serve entirely credibly in this role. EPA next called upon Dr. Roy Albert, a prominent scientist at New York University, to work with the agency's in-house Carcinogen Assessment Group on drawing up the 1976 "interim procedures." This time the agency's own experts retained substantial control over the actual work of guideline development, and again the results lacked

[37] Leslie Roberts, "Risk Assessors Taken to Task," *Science,* 1990, *247*:1173.
[38] Brickman, Jasanoff, and Ilgen, *Controlling Chemicals* (cit. n. 26), pp. 191–192.
[39] Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 186–193.
[40] Efron, *The Apocalyptics* (cit. n. 25), p. 83.

persuasive power. EPA's blindness toward the need for impartial scientific support continued at least until 1981, when the agency tried to justify its laissez-faire policy on formaldehyde, a suspected carcinogen, by appealing to a "science court" composed mainly of industry experts and agency staff.[41]

The furor provoked by the formaldehyde episode and other scandals during the early Reagan presidency forced EPA to look more closely at the possibility of enlisting its own Science Advisory Board (SAB) more actively in the process of legitimation. Originally established at EPA's own initiative, the board gained in stature after Congress in 1978 codified its mission through amendments to the Energy Research, Development, and Demonstration Authorization Act.[42] SAB's relations with EPA, however, remained equivocal through the administration of Anne Gorsuch, a Reagan political appointee. The collaboration reached a low point in 1977, when EPA tried to bypass a hostile SAB subcommittee by asking an ad hoc panel of experts, headed by Dr. Carl M. Shy, to ratify its proposed ozone standard.[43] Shy was known to have strong views about the need for stricter controls on ozone, and this maneuver did little to enhance EPA's reputation for impartial scientific expertise. A still more ignominious moment came in 1983, when a House investigation disclosed a "hit list" of scientists whom EPA staff had allegedly considered too dangerously proenvironment for appointment to the SAB.[44]

Gorsuch's departure from EPA ushered in an era of more harmonious interaction with the SAB.[45] The advantages of the new cooperation became evident during the 1986 revision of the risk assessment guidelines. EPA's attempt to publish the revised guidelines had been stalled for some time at the OMB, where Wendy Lee Gramm, administrator of the Office of Information and Regulatory Affairs (OIRA), sought to prevent their issuance on the ground that they would not adequately inform decision makers of the uncertainties surrounding risk assessment.[46] Underlying OMB's recalcitrance was a firm conviction that EPA's default provisions were still too conservative, that is, they tended to overstate the risk to an unacceptable degree. OMB officials accordingly proposed to rewrite four key guidelines with the objective of bringing cancer risk assessment closer to their view of reality. EPA eventually freed itself from OMB's proposed constraints with assistance from the SAB, as well as Representative John Dingell's powerful

[41] Bette Hileman, "Formaldehyde," *Environmental Science and Technology,* 1982, *16*:544A. For criticism of the agency see Frederica Perera and Catherine Petito, "Formaldehyde: A Question of Cancer Policy," *Science,* 1982, *216*:1285–1291; and Nicholas Ashford, C. William Ryan, and Charles Caldart, "A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking," *Harvard Environmental Law Review,* 1983, *7*:297–370. See also House Committee on Science and Technology, *Formaldehyde: Review of Scientific Basis of EPA's Carcinogenic Risk Assessment,* 97th Cong., 2nd sess. (1982).

[42] Terry F. Yosie, "The EPA Science Advisory Board," in *Harnessing Science for Environmental Regulation,* ed. John D. Graham (New York: Praeger, 1991), pp. 11–12.

[43] R. Shep Melnick, *Regulation and the Courts: The Case of the Clean Air Act* (Washington, D.C.: Brookings Institution, 1983), pp. 286–287.

[44] Eliot Marshall, "Hit List at EPA?" *Science,* 1983, *219*:1303.

[45] Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 89–95.

[46] Wendy L. Gramm (Administrator, Office of Information and Regulatory Affairs, OMB) to Lee Thomas (Administrator, EPA) 12 Aug. 1986, Environmental Protection Agency files, Washington, D.C.

House committee. The fact that the SAB had peer-reviewed and approved the guidelines was held out as persuasive evidence of their scientific validity.[47]

III. RESTORING THE BOUNDARIES BETWEEN SCIENCE AND POLICY

The turbulent history of cancer risk assessment exemplifies the difficulties EPA faced in spanning the divide between science and policy. The effort to articulate its thought processes proved to be much more damaging to its credibility than the agency had initially envisaged. The preparation of risk assessment guidelines turned into a complex process of analytical deconstruction that revealed the large core of interpretative flexibility buried within each "factual" determination about chemical carcinogenicity. As an institutional watchdog over industry, EPA could not escape the charges that its particular interpretative choices were conditioned by an empirically unsupported bias toward overstating, and overregulating, risks from industrial chemicals.

The inexorable progression from stating a knowledge claim (substance X is a carcinogen) to analytical deconstruction to imputations of political bias left EPA scientifically as well as politically in an extraordinarily vulnerable position. Mere claims of expertise were no longer sufficient to restore the agency's authority. EPA was committed by law and cultural tradition to making rational decisions, and for the American public rationality meant that science should be kept distinct from politics and policy. Public confidence in regulation depended in part on the preservation of clear boundaries between scientific analysis and political judgment, a goal that risk assessment seemed chronically unable to meet. Attempts to restore the boundaries therefore became an integral part of environmental decision making, but like all other components of the process, boundary drawing itself turned out to be an intensely political undertaking. Not only EPA, but Congress, industry, and the scientific community participated in the boundary exercises, pursuing their objectives by both rhetorical and institutional means.

Rhetorical Constructs and Political Realities

Occasionally, in moments of unusual asperity, the Supreme Court has accused the parties before it of changing positions "as nimbly as if dancing a quadrille."[48] That description applies with equal felicity to EPA's early attempts to state whether its cancer principles should be treated as science or policy. When Velsicol, the manufacturer of heptachlor and chlordane, asked EPA to submit the principles to the National Academy of Sciences (NAS) for peer review, the agency responded by stressing their policy content. For example, the authorities that EPA cited in support of the principles were its own policy announcements in the *Federal Register* rather than publications in scientific journals. Yet, in a contrary move, EPA also sought to have the principles judicially noticed as "facts" by the administrative law judge in proceedings to cancel the registrations of the two

[47] Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 192–193; and Yosie, "The EPA Science Advisory Board" (cit. n. 42), p. 19.

[48] *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, U.S. Supreme Court Reports*, 1978, *435*:519, 540.

pesticides.[49] A more balanced and realistic position emerged some ten years later (and then only implicitly), when EPA administrator Lee Thomas replied to criticisms from Gramm of OIRA by saying that the risk assessment guidelines "were developed with full participation of scientists from government, academe, industry and public interest groups."[50] By acknowledging the role of scientific as well as political actors, this statement finally gave an honest appraisal of the mixed character of cancer risk assessment.

Similar vacillation about the nature of risk assessment marked the pronouncements of other interested actors, including scientists and government agencies. A revealing exchange, which I have described elsewhere in full, took place between Dr. Norton Nelson, later chairman of the SAB executive committee, and a House subcommittee investigating federal policies for regulating carcinogens. Nelson at first repudiated the idea of a "cancer policy formulated within a purely administrative framework of OSTP and the federal agencies." Such an approach, he indicated, would lack scientific credibility, and he recommended assigning the task of guideline development to a nongovernmental body such as the NAS. Moments later, however, Nelson approvingly cited the risk assessment principles developed in the late 1970s by the Interagency Regulatory Liaison Group (IRLG), a policy-coordinating unit active during the Carter administration. Congressman Don Ritter, a Republican from Pennsylvania, quickly seized on the apparent contradiction: "I should like to point out that the IRLG, which you seem to hold in very high esteem, was also a governmental body, an interagency body."[51]

A recent critical study of EPA's performance accuses IRLG itself of similarly misleading boundary drawing. The IRLG, according to this view, conveyed a falsely scientific image by covering up its policy choices in a cloak of misleading language. It took for granted "that questions about which tests and methods to use are scientific issues that can be decided on a technical basis," even though its proposals were replete with social implications:

> In summary, the IRLG document posed what was really a set of mixed scientific and policy questions as if it were just a set of scientific issues. The critical political judgments were bundled up in and concealed by words like *conservative, prudent, significant,* and *reliably.* No concern with the costs of false-positive results or of overestimating risks was expressed, nor indeed is the reader's attention ever called to these issues.[52]

If IRLG erred in the direction of making its policy conclusions appear too "scientific," then OMB—which emerged as the government's chief interagency coordinator in the 1980s—elected the opposite course, that is, to play down and even deny the scientific character of EPA's risk assessment practices. In its 1991 review of U.S. regulatory programs, OMB reiterated the charge that current risk assessment models and assumptions reflected a conservative bias. More point-

[49] Jasanoff, "The Problem of Rationality" (cit. n. 34), pp. 168–169.

[50] Lee M. Thomas to Wendy L. Gramm, 22 Aug. 1986, EPA files, Washington, D.C.

[51] House Committee on Energy and Commerce, Subcommittee on Commerce, Transportation, and Tourism, *Control of Carcinogens in the Environment,* 98th Cong., 1st sess. (1983), pp. 72 (Nelson), 84 (Ritter). For a full account see Sheila Jasanoff, "Contested Boundaries in Policy-Relevant Science," *Social Studies of Science,* 1987, *17*:195–230, pp. 222–223.

[52] Marc K. Landy, Marc J. Roberts, and Stephen R. Thomas, *The Environmental Protection Agency: Asking the Wrong Questions* (New York: Oxford Univ. Press, 1990), pp. 196, 198.

edly, OMB observed that "a scientific basis for several of the most critical models and assumptions simply does not exist" and that "there is no accepted scientific basis for the assumption that results can be meaningfully extrapolated from test animals to humans."[53]

Steering between these extremes, the National Research Council sought to provide a balanced and accurate characterization of risk assessment and to recommend how federal agencies should carry out the process. In this spirit, NRC's 1983 report and the accompanying working papers acknowledged that risk assessment unavoidably combined elements of both science and policy. Yet even this relatively impartial study failed to state a completely coherent set of conclusions. The NRC report became best known for its recommendation that regulatory agencies should "take steps to maintain a clear conceptual distinction between assessment of risks and consideration of management alternatives."[54] Additional references to the vital necessity of maintaining such a distinction were sprinkled throughout the report. But the NRC committee's own analysis of the complexities of risk assessment underscored the impracticability of cleanly separating science from policy and provided an intriguing counterpoint to the theme of separation. Most significantly, the report rejected the notion that risk assessments should be carried out by a new, centralized, scientific body rather than by the individual regulatory agencies. The conclusion that regulatory agencies should remain the primary locus for the assessment as well as the management of risk was hardly consistent with the goal of strict functional separation. The extracts presented in Table 1 capture some of the report's dialectical waverings on the issue of separating risk assessment from risk management or science from policy.

Institutional Adjustments

While rhetorical boundary drawing sometimes served EPA as an effective short-term defense, it clearly was not a viable route to achieving long-term scientific credibility. By the mid 1980s charges were mounting that the agency was misrepresenting costly political choices as exercises of scientific judgment. Typical of the new criticism was R. Shep Melnick's attack on EPA's interpretation of "adverse health effects" when setting air quality standards. Melnick took EPA to task for maintaining, in the face of the evidence, that there were "thresholds" below which exposure to air pollutants would produce no adverse effects. The agency, in Melnick's view, was justifying this scientifically untenable position through a form of disingenuous boundary work, masking policy as science: "The EPA thus manages to get the best of both worlds: standard setting is not a political act, but a technical task that must be performed by an expert agency; yet the uncertainty of the task frees the agency from the dictates of scientific evidence and its political executives from responsibility for the economic and social consequences of its determinations."[55] This analysis of EPA's actions parallels the critique quoted

[53] President's Office, *U.S. Regulatory Program* (cit. n. 19), p. 15.

[54] NRC, *Risk Assessment in the Federal Government* (cit. n. 13), p. 7. For the difficulty of that distinction see esp. Lawrence E. McCray, "An Anatomy of Risk Assessment: Scientific and Extra-Scientific Components in the Assessment of Scientific Data on Cancer Risks," in Working Papers, *ibid.*, pp. 83–101.

[55] Melnick, *Regulation and the Courts* (cit. n. 43), p. 257.

above of IRLG's work on cancer risk assessment. Both examples suggest that in the antiregulatory, cost-conscious environment of the 1980s, policy-making agencies could no longer hope to shelter their discretionary judgments at the borderline of science and policy behind uncontested claims of scientific expertise.

The erosion of EPA's expert status led to virtual paralysis in some of the agency's most controversial regulatory programs, including the Clean Air Act's provision for controlling hazardous air pollutants. EPA had tried in 1976 and again in 1985 to bypass the analytical difficulties of which Melnick complained by setting the standard for vinyl chloride, a nonthreshold pollutant, on the basis of technological feasibility. Since EPA did not admit that there was any "safe" level of exposure to vinyl chloride, it was simpler for the agency to demand the application of the "best available technology" than to wrestle with the elusive statutory concept of "an ample margin of safety." Each time, however, a lawsuit by the Natural Resources Defense Council (NRDC) compelled the agency to give up its technology-based approach in favor of a renewed effort to define safety. The clash between EPA's legal obligations and its risk assessment capabilities brought the program to an almost complete halt. Following NRDC's second lawsuit, only one further standard was issued before Congress finally mandated in 1990 that "maximum achievable control technology" should be used to control 189 listed hazardous air pollutants.[56]

Sorry experiences such as this forced EPA to cast around for more durable methods of regaining the scientific high ground in its efforts to deal with risk. Following Ruckelshaus's return as administrator, the agency appeared to recognize that scientific advice could serve as a powerful resource in shoring up actions at the boundary between science and politics. By obtaining ratification from an impartial expert body, EPA could provide prima facie evidence that its decisions were supportable on scientific grounds. Risk assessments, in particular, could be made to look more scientific simply because they had been reviewed and found acceptable by reputable scientists located outside the agency.

Enlisting the SAB in the risk assessment dispute with OIRA was an early symptom of EPA's thoroughgoing change of heart on the need for external scientific advice. The SAB's increasingly important role in EPA's decision making from 1984 onwards can be charted through increases in the board's budget and the number of reviews committed to it each year.[57] Interest in cooperating with the SAB grew even more pronounced during William Reilly's tenure as EPA administrator. Reilly and his top aides appeared intent on showing that EPA's course could be directed by science rather than by the vagaries of public fear or congressional politics. Nowhere was the scientistic urge more clearly manifested than in the attempt to reorder the agency's priorities by means of a scientifically reliable classification of environmental risks.

Toward the end of Lee Thomas's administration, seventy-five of EPA's senior staff members undertook a heroic effort to identify the biggest problems confronting the agency. Pooling often scanty data with large doses of professional

[56] *NRDC v. EPA, Fed. Rep.*, 2nd ser., *824*:1146 (D.C. Cir. 1987); and Clean Air Act Amendments of 1990, Title III.

[57] Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 79–80.

Table 1. Separating Science from Policy
(Extracts from National Research Council, *Risk Assessment in the Federal Government*)

Science and policy should be separate	Science and policy are connected
Even the *perception* that risk management considerations are influencing the conduct of risk assessment in an important way will cause the assessment and regulatory decisions based on them to lack credibility (p. 49).	[P]olicy considerations inevitably affect, and perhaps determine, some of the choices among inference options (p. 33).
Before an agency decides whether a substance should or should not be regulated as a health hazard, a detailed and comprehensive written risk assessment should be prepared and made publicly accessible. This written assessment should clearly distinguish between the scientific basis and the policy basis for the agency's conclusions (p. 153).	The choices encountered in risk assessment rest, to various degrees, on a mixture of scientific fact and consensus, on informed scientific judgment, and on policy determinations (the appropriate degree of conservatism). . . . That a scientist makes the choices does not render the judgments devoid of policy implications (p. 36).
A frequent deficiency of risk assessments is the failure to distinguish clearly between scientific and policy considerations in risk assessment (p. 164).	Guidelines unavoidably embody both scientific knowledge and risk assessment policy (p. 76).

judgment, they produced a tentative ranking of thirty-one such issues. Their report, appropriately entitled *Unfinished Business,* became the springboard for an ambitious follow-up study carried out by the SAB. Shortly after Reilly took office in 1989, he asked the SAB in effect to peer review the earlier report: "To go over the data again, see whether they agreed with the methodology and rankings, and, if not, to come up with their own."[58] To perform these tasks, the SAB set up a Relative Risk Reduction Strategies Committee (RRRSC) of forty-five experts, most but not all of whom were scientists. The RRRSC in turn constituted itself into three subcommittees to look at ecology and welfare, human health, and strategic options for reducing risk.

The RRRSC's report, *Reducing Risk,* was quickly heralded as a manifesto for the agency that EPA hoped to become in the 1990s. Looking more scientific was an important part of EPA's new agenda, and public responses to the report suggested that this effect was being achieved. For example, an article in *Science* commenting on the report's release was entitled "Counting on Science at EPA." The SAB's involvement was critical in bringing about this change of perception, even though, ironically, the work that the RRRSC did in preparing the report was by the committee's own admission "more policy-oriented than is usually the case" for SAB analyses.[59]

[58] Leslie Roberts, "Counting on Science at EPA," *Science,* 1990, *249*:616–618, on p. 618. For the report see EPA, *Unfinished Business: A Comparative Assessment of Environmental Problems* (Washington, D.C., 1987).

[59] Raymond Loehr and Jonathan Lash (RRRSC cochairs) to William Reilly, in EPA Science Advisory Board, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* (Washington,

Like the authors of *Unfinished Business,* the RRRSC acknowledged that scientific uncertainties and methodological inadequacies were involved in any attempt to evaluate relative risks, so that conclusions would necessarily require the exercise of professional judgment. As if to underline this point, the subcommittees on ecology and welfare and on human health divided in their approaches to ranking risks. The former attempted a kind of ordering by grouping environmental problems into high-, medium-, and low-risk areas, while the latter merely identified areas where existing data indicated that the risks could be relatively high. Overall the committee concluded "that subjective values always will—and should—influence the ranking of relative environmental risks, no matter how sophisticated the technical and analytical tools become."[60]

These results were not in themselves revolutionary, for they tracked the experiences of many previous agency groups and expert panels concerned with evaluating risk, such as the committee that wrote the NRC's 1983 risk assessment report. Scientists as well as social scientists had repeatedly observed that facts and values commingle in the analysis of environmental risks.[61] Professional differences of the kind that arose between the ecology and human health subcommittees of the RRRSC likewise were hardly unknown in the universe of environmental regulation. The more remarkable point for our purposes is that *Reducing Risk* was widely regarded as a *scientific* reevaluation of EPA's priorities, in spite of the concededly judgmental and value-laden aspects of the exercise. The fact that the study was conducted by an independent scientific body proved to be of critical importance in extending the legitimating aura of "science" to an activity that so clearly mingled science and policy.

EPA's efforts to refurbish its scientific image led to additional initiatives to enlist outside scientists. In late 1980 the agency joined hands with one of its most persistent adversaries, the automotive industry, to form the Health Effects Institute (HEI), a nonprofit corporation designed to fund research on the health effects of automobile emissions.[62] Two simple objectives provided the *raison d'être* for HEI. First, the institute sought to reduce adversarial conflicts over science by securing joint research funding from EPA and industry. Second, HEI attempted to guarantee its scientific autonomy through a system of advisory panels and review procedures that buffered its research programs against close identification with the interests of either sponsoring party.

D.C., 1990), p. ii; and Roberts, "Counting on Science" (cit. n. 58). SAB committees are ordinarily careful to define their role as scientific even when they are dealing with elements of policy: see Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 95–97. In this case, however, the selection of a policymaker, Lash, as cochair, as well as the creation of a strategic options subcommittee, may have predisposed the RRRSC to be more forthcoming about the nature of its analysis.

[60] EPA, *Reducing Risk,* p. 8; on the subcommittees see p. 13. See also Roberts, "Counting on Science" (cit. n. 58), p. 617.

[61] For scientists' views on this point, see, e.g., Alice S. Whittemore, "Facts and Values in Risk Analysis for Environmental Toxicants," *Risk Analysis,* 1983, *3*:23–33; and Alvin M. Weinberg, "Science and Its Limits: The Regulator's Dilemma," *Issues in Science and Technology,* Vol. II, Fall 1985, pp. 65–67. For a range of views from the social sciences see Branden B. Johnson and Vincent T. Covello, eds., *The Social and Cultural Construction of Risk* (Dordrecht/Boston: Reidel, 1987).

[62] For detailed accounts of HEI's organization and functioning see Thomas P. Grumbly, "The Health Effects Institute," in *Harnessing Science,* ed. Graham (cit. n. 42), pp. 39–62; and Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 209–216.

By the end of the 1980s HEI had begun to produce results that firmly established its claim to scientific integrity. An investigation by the General Accounting Office in 1986 concluded that HEI had "made progress in establishing itself as an independent, objective, and credible sponsor of high quality research."[63] A multicenter study of the health effects of carbon monoxide, completed and published in the *New England Journal of Medicine* in 1989, exemplifies HEI's achievements. EPA had called upon HEI to perform the study after problems were uncovered in carbon monoxide research carried out by Dr. Wilbert S. Aronow, an agency consultant.[64] Despite this unfortunate history and the study's relevance to policy, HEI was able to produce scientific results that did not lead to political controversy. This accomplishment made an impression on federal legislators perennially concerned about EPA's scientific credibility.

Like Archilochus's hedgehog, Congress in the early 1970s knew one great thing about environmental protection: that risks should be controlled before they had the time to ripen into visible harm. But like the Greek poet's fox, Congress by the late 1970s had come to know many things about the implementation of risk-based environmental programs, and its legislative actions were frequently and specifically directed toward rectifying the failings that it perceived. Complaints about EPA's scientific inadequacies, in particular, reached willing ears on Capitol Hill, and Congress became an active participant in limiting EPA's discretion to produce and interpret science. The techniques it chose were largely procedural and were often tied to the use of external scientific committees.

Incremental learning explains, for instance, why Congress wrote into the 1986 amendments to the Superfund law a peer-review requirement for studies done at toxic waste disposal sites. Applicable both to pilot studies of health effects and to full-scale epidemiological studies, this provision was designed to forestall disputes of the kind that arose in connection with the EPA-sponsored investigation of chromosomal damage at Love Canal. Similarly, in 1980 Congress passed amendments to the federal pesticide law calling upon EPA to submit major scientific studies to its Scientific Advisory Panel for review and to seek the panel's comments on decisions to suspend any pesticide. Both requirements were prompted by EPA's controversial decision to bypass the panel in evaluating the risks of 2,4,5-T.[65]

In several instances Congress took up EPA's own initiatives with respect to scientific review and institutionalized them more securely. Thus the Science Advisory Board, originally established by internal administrative action, received legislative authorization in 1978 and was periodically given new responsibilities by Congress in response to perceived needs. In 1977, for example, amendments to the Clean Air Act required EPA to establish a standing committee to review the basis for ambient air quality standards; this Clean Air Scientific Advisory Com-

[63] General Accounting Office, *Air Quality Standards: The Role of the Health Effects Institute in Conducting Research* (Washington, D.C.: GAO, 1986), p. 37.

[64] Elizabeth N. Allred et al., "Short-Term Effects of Carbon Monoxide Exposure on the Exercise Performance of Subjects with Coronary Artery Disease," *New England Journal of Medicine,* 1989, *321*:1426–1432. The study team's report and the report of HEI's Health Review Committee were also published together as HEI Research Report Number 25, Cambridge, Mass., November 1989. On the episode see Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 120–121.

[65] Jasanoff, *The Fifth Branch,* pp. 35 (Love Canal), 125 (2,4,5-T). See also the discussion in notes 18 and 19 above.

mittee was eventually constituted as a permanent subcommittee of the SAB. In 1986, in amendments to the Safe Drinking Water Act, Congress asked EPA to consult with the SAB before proposing maximum contaminant goals and regulations for achieving them.[66] The Health Effects Institute, another EPA innovation, also received independent recognition from Congress. In its 1989 appropriations bill for EPA, Congress included a line item of $2 million for research on asbestos, which it specified was to be carried out by HEI. The institute responded by forming a new, nonprofit corporation organized on the same principles as the parent body but funded by a grant from EPA and matching funds from industry.[67]

Congress on occasion also asked EPA and other regulatory agencies to seek scientific validation from the National Academy of Sciences (NAS) and the National Research Council. These requests were comparable to studies that the agencies periodically commissioned from NAS or NRC at their own initiative. The NRC's much cited 1983 report on risk assessment, for example, was prompted by a congressional directive to the Food and Drug Administration to consider alternative institutional approaches to evaluating risks. Other congressionally mandated studies of risk assessment include a 1977 survey of EPA's processes of acquiring and using scientific and technical information, a series of studies commissioned in the same year of drinking water and health, a 1990 study to evaluate alternative methods of tracking toxic substances at industrial facilities, and a 1991 study of the desirability of a program for monitoring toxics in human tissue. In the Clean Air Act Amendments of 1990, Congress requested a review by the NAS of EPA's methodology for assessing the carcinogenic risk of hazardous air pollutants. EPA's own claims to expertise clearly did not carry enough weight with the legislature to preclude the need for certification by a more prestigious scientific agency.

IV. CLOSURE: RECREATING THE FACTS

Despite the growing preoccupation with analytical and institutional processes in the validation of policy-relevant science, ultimately it is still a fact or claim that provides the hook for regulatory action. EPA cannot tighten emission controls on a pollutant or keep a toxic product off the market unless it is able to state a risk claim with reasonable assurance—for example, that the compound "presents an unreasonable risk" or "is a carcinogen." But in a system so uncompromisingly tilted toward the deconstruction of science, how can the agency close off debate to the extent necessary for stating an authoritative claim?[68] EPA's experiences suggest that process, appropriately tailored, again holds the answer. As in the case of the 1986 cancer risk assessment guidelines, EPA projects scientific authority most convincingly where its decision-making process integrates the demands of both science and politics.

[66] Safe Drinking Water Act, Section 1412 (e), as revised by Public Law 99-339 (1986).

[67] Health Effects Institute–Asbestos Research, News Release, Cambridge, Mass., 9 Oct. 1989.

[68] A number of analysts have observed that mere accumulation of scientific knowledge is not necessarily enough to close regulatory controversies. See Collingridge and Reeve, *Science Speaks to Power* (cit. n. 8), for a particularly skeptical treatment of this issue. See also John D. Graham, Laura C. Green and Marc J. Roberts, *In Search of Safety: Chemicals and Cancer Risk* (Cambridge, Mass.: Harvard Univ. Press, 1988), pp. 190–198.

EPA's decision making on formaldehyde illustrates the importance of devising politically as well as scientifically credible closure mechanisms. During the Gorsuch administration the agency's claim that formaldehyde did not present a significant cancer risk to humans foundered, as we have seen, because the so-called science court convened by the agency to test that claim seemed to favor industry's interests blatantly. Subsequently, the formaldehyde industry attempted to regain through science the momentum that it had lost through politics. Industry representatives claimed, in particular, that new scientific discoveries about the pharmacokinetics of formaldehyde explained the strongly carcinogenic response in rats and indicated at the same time why the compound would be less risky to humans exposed to substantially lower dose levels.[69] Here, finally, was an argument that appeared to justify the policy-relevant claim that formaldehyde was not a human carcinogen, the very position that industry had tried unsuccessfully to impress on EPA in the early 1980s.

EPA, however, showed no inclination to exonerate formaldehyde on the basis of industry's new scientific allegations. Agency scientists argued in brief that the pharmacokinetic data, though suggestive, had not gained sufficient scientific standing to warrant incorporation into existing risk assessment models. But EPA by now was sensitive to the need for independent validation of its scientific conclusions, and it called upon the SAB to review its assessment of formaldehyde. The SAB proved to be a demanding ally, at once skeptical of EPA's motives and more receptive to the claims of new science. Unwilling to accept EPA's bare assertion concerning the reliability of the pharmacokinetic data, the SAB asked the agency to collect stronger scientific support for its determination. EPA complied by convening an ad hoc panel of experts to review the studies on delivered dose, and this body in turn essentially reaffirmed the agency's conservative position. The new results, the review panel concluded, marked an "important first step" toward better dose measurements, but they required further validation before they could properly serve as a basis for risk assessment.[70] Thus a process that blended the political legitimacy of wide consultation with the scientific legitimacy of peer review enabled EPA to have the last word (that is, to achieve closure) on the touchy subject of the human carcinogenicity of formaldehyde.

A similar blending of the norms of scientific and administrative practice marked EPA's efforts to revise its risk assessment model for the highly toxic compound dioxin. The agency had maintained for many years that not enough was known about the molecular action of dioxin to justify a departure from the linear extrapolation model that the agency normally applies to chemicals having no known safe threshold of exposure. EPA's position on this issue was sharply at odds with that of European and Canadian dioxin regulators, who had long assumed that the substance was not risky to humans at low doses. But there was no indication that EPA might reconsider its position until a scientific meeting held at Cold Spring Harbor's Banbury Center concluded that dioxin must first bind to

[69] Studies conducted by the Chemical Industry Institute of Toxicology, an industry-funded scientific research organization, indicated that the amount of formaldehyde incorporated into DNA in the nasal mucosa of rats showed a discontinuity at 2 ppm. At this exposure, the "delivered dose," as measured by DNA binding, was about four times lower than would have been expected from a straight-line extrapolation from higher exposures. Graham, Green, and Roberts, *In Search of Safety,* p. 49.

[70] Jasanoff, *The Fifth Branch* (cit. n. 7), pp. 204–205.

and activate a receptor before it produces any toxic effects. This international meeting—whose organizers ironically included not only scientists but prominent regulators from both the United States and Europe—finally allowed EPA to begin working on a new risk assessment model for dioxin. The Banbury consensus conferred scientific respectability on a move that EPA might otherwise have rejected as too politically risky. Yet EPA officials acknowledged that they could not consummate a policy change without paying careful attention to established decision-making procedures, including extensive interagency consultation and review by the SAB.[71]

A common feature of both the formaldehyde and dioxin cases was the creation of a credible scientific forum—the ad hoc review panel and the Banbury Center meeting, respectively—where the scientific questions critical to policy-making appeared to have been definitively, and impartially, answered. In each case a collective decision among scientists with no apparent political stake in the matter at least temporarily "black boxed" issues that had long vexed the agency. Although not everyone was satisfied, the deconstructive pressures of the regulatory process were neutralized for the moment.

When EPA manages to attain this type of closure, stable at once in scientific and political terms, it finally converts process back into "fact" and thereby arms itself with a powerful basis for action. Such happy endings, however, can only be expected when the issues before the agency are relatively narrow and focused, and hence ripe for resolution in an authoritative expert forum. It is probably no accident that both formaldehyde and dioxin were well-studied substances that had engaged the attention of bounded communities of experts and were associated with an increasingly more circumscribed set of scientific uncertainties. These factors made possible the formation of a consensus among scientists and a redrawing of the boundary between science and policy, both important prerequisites for legitimating regulatory action. Closure may be significantly harder to achieve in cases where the scientific dispute cannot so readily be isolated from the surrounding political matrix. The seemingly endless controversies about the conservatism of EPA's cancer risk assessment guidelines and the proper interpretation of animal bioassay data provide a case in point.[72]

CONCLUSION

Science, in Ezrahi's view, has provided the legitimation strategy for democratic politics in our time by linking accountability to the ideas of transparency and of public witnessing. EPA's efforts to build support for environmental regulation underscore the limitations of this approach when science itself is part of the matter

[71] Leslie Roberts, "Dioxin Risks Revisited," *Science,* 1991, *251*:624; and Roberts, "EPA Moves to Reassess the Risk of Dioxin," *ibid.,* p. 911.

[72] Support for this observation can be found in a series of editorials, articles, and letters that appeared in *Science* in the winter of 1990–1991. See, in 1990, Philip H. Abelson, "Testing for Carcinogens with Rodents," *249*:1357; Abelson, "Incorporation of New Science into Risk Assessment," *250*:1497; and Jean Marx, "Animal Carcinogen Testing Challenged," *250*:743–745. See also the following exchanges of letters, in 1990: "Carcinogens and Human Health: Part I," *250*:1644–1646; in 1991: "Carcinogens and Human Health: Part II," *251*:10–13; "Carcinogens and Human Health: Part III," *251*:606–608; "Carcinogen Models," *251*:142–144; and "Carcinogenesis Mechanisms: The Debate Continues," *252*:902–904.

that must be made transparent, for science too closely witnessed becomes indistinguishable from the political goals to which it is harnessed. Particularly in the area of risk management, the attempt to make the agency's thought processes fully visible to the spectator public has frequently led to political stalemate. The unpacking of factual claims into their constituent components has reversed the ordinary processes of scientific fact building, leaving EPA without a credible foundation for regulatory action. Indeed, the naked exercise of discretion by the agency has spurred other actors to reclaim the interpretative terrain on their own terms, thereby merging the debate over policy-relevant science with a wider political debate.

For EPA, one of the bitter lessons of its first twenty years was that transparency alone is worth little in the public political arena unless it is accompanied by factual claims that can resist deconstruction. Environmental regulation cannot proceed, as the agency discovered to its dismay, unless one can state with reasonable authority factual claims that are relevant to policy: for example, that "substance X is a carcinogen," that "substance Y presents no risk to human beings," or that "there is a safe threshold level of exposure to substance Z." In its earlier years the agency sought to defend its claims against skeptical assault primarily by asserting its specialized expertise, but although this approach won initial support from the courts, it failed to protect the agency from the more concerted opposition that it confronted after the "Reagan revolution" of 1980. Rhetorical boundary drawing proved to be an inadequate instrument for certifying as "science" decisions that fell on the murky boundary between science and policy. In an era when the authority of science was under attack on many fronts, EPA's deconstructive approach to science heightened rather than quieted public unease.

The period of environmental decision making that began in the mid 1980s can rightly be seen as a return to fact making, but to fact making with a difference. On the one hand, EPA recognized that it could no longer serve as the exclusive, or even the primary, forum for the construction (or reconstruction) of policy-relevant facts. The basis for making expert claims was renegotiated as the agency increasingly relied on satellite scientific bodies—HEI, the SAB, the Banbury meeting—to originate or certify claims that would stand up to political testing. On the other hand, these institutions were themselves required to be sufficiently sensitive to the norms of politics to maintain scientific credibility. Their impartiality, too, had to be secured through administrative and political controls, such as novel funding arrangements, interest-group representation, and open meetings, rather than by mere assertions of superior scientific expertise. It is a final irony of environmental decision making that, in the effort to keep politics distinct from science, the processes of scientific fact making so freely accommodated themselves to the demands of politics.