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## Introduction

Over the past twenty years, federal regulatory agencies have emerged as a critically important locus for scientific fact-finding and adjudicating controversies about science. In implementing programs of health, safety and environmental regulation, agency experts must review and assess the state of scientific knowledge, identify areas of consensus to the best of their ability, and resolve uncertain evidence consistently with applicable statutory mandates. These exercises are as public as they are contentious, and agencies are frequently charged either with technical incompetence (using "bad science") or with subordinating science to political ends.[1]

Both problems, it is widely felt, can be controlled through greater reliance on the independent scientific community. Conventional wisdom holds that increased participation by non-governmental scientists in the regulatory process will improve not only the quality, but also the objectivity of policy-relevant science. Accordingly, proposals to strengthen the role of scientific advisory committees — for example, through legally mandated peer review — have received considerable attention in discussions of regulatory reform.[2] The idea that scientific

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1 *See, e.g.*, Kristin S. Shrader-Frechette, *Risk Estimation and Expert Judgment: The Case of Yucca Mountain*, 3 RISK 293, 314 (1992).

2 NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983); AMERICAN CHEMICAL SOCIETY AND THE CONSERVATION FOUNDATION, ISSUES IN PEER REVIEW OF THE SCIENTIFIC BASIS FOR REGULATORY DECISIONS (1985); Thomas S. Burack, *Of Reliable Science:*

issues should be left to scientists continually resurfaces in the regulatory arena, most notably in the oft-repeated injunction that risk assessment should be kept strictly separate from risk management.[3] Some, indeed, have argued that a science court or similar adjudicatory procedure would be the most appropriate procedural forum for resolving the technical uncertainties that arise in the course of regulation.[4]

My aim in this paper is to compare four established approaches to incorporating science into regulatory decisionmaking, one of which is very similar to the classic science court proposal. I will argue generally that adversarial procedures like the science court are less effective in achieving regulatory objectives than procedures that are more sensitive to the distinctive characteristics of regulatory science. The paper consists of three parts, raising analytic, descriptive and normative issues, respectively. In the first part, I characterize regulatory science using concepts derived from social studies of science, including recent work on scientific advice and peer review. In the second part, I review four brief regulatory histories in order to illustrate the institutional and procedural mechanisms that agencies most commonly use in processing scientific information. In the final section, I compare these competing approaches and evaluate the more court-like proceedings in relation to less adversarial procedures for assessing regulatory science.

## The Characteristics of Regulatory Science

To understand why some approaches to evaluating science work better than others in the regulatory setting, it is essential to begin with an inquiry into science itself. What, specifically, can we glean about the science that is used for regulatory purposes (hereafter "regulatory science") from currently accepted accounts of the nature of scientific

*Scientific Peer Review, Federal Regulatory Agencies, and the Courts*, 7 VA. J. NAT. RESOURCES L. 27 (1987).

3 *See, e.g.*, Helena Szejwald Brown & Robert L. Goble, *The Role of Scientists in Risk Assessment*, 1 RISK 283 (1990).

4 *See, e.g.*, Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, *The Science Court Experiment: An Interim Report*, reprinted *infra* at 179. *See also*, Alvin Weinberg, *Science and Trans-Science*, 10 MINERVA 209 (1972) (suggesting that procedures borrowed from the law are best suited to resolving trans-scientific questions).

claims and of the sources of conflict, consensus and authority in science.

An important insight emerging from the social studies of science in recent years is that scientific claims are to a large extent "socially constructed."[5] This argument holds, in brief, that claims in science do not simply mirror nature but are subject to numerous social influences. These include, most obviously, the theoretical and methodological constraints imposed by prevailing scientific paradigms in a given discipline or historical period. More controversially, however, scientific claims also seem to incorporate factors unrelated to the presumed cognitive concerns of science, such as the institutional and political interests of scientists and their organizations. Evidence for the social construction of scientific claims derives from several sources, including the study of scientific controversies, ethnographic studies of laboratories and historical investigations of the rise and fall of scientific theories.[6]

Unlike proponents of "political capture," who attribute scientific disputes to intentional manipulation of facts by political interests, advocates of social construction do not insist that ideological differences among experts are the sole determinant of variations in the interpretation of data. Evidence from social studies of science suggests, instead, that expert disputes can arise out of "honest" differences linked to disciplinary training, institutional affiliation, or professional status. For example, molecular biologists, toxicologists and epidemiologists may differ in their definitions of what constitutes an adequately controlled experiment. And a scientist committed to maintaining disciplinary rigor may publicly insist that only the use of contemporary controls represents legitimate science, even though practices within the profession show wide variation, with many practitioners using a mix of both historical and contemporaneous controls.

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5 *See, e.g.*, SCIENCE OBSERVED (Karin D. Knorr-Cetina & Michael Mulkay eds. 1983). On the social construction of risk, *see* THE SOCIAL AND CULTURAL CONSTRUCTION OF RISK (Branden Johnson & Vincent Covello eds. 1987).

6 Major works in these areas include CONTROVERSY (Dorothy Nelkin ed., 2d ed. 1984); BRUNO LATOUR & STEVE WOOLGAR, LABORATORY LIFE (1986); THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (1962).

These findings have important implications for science in the policy process, for they lead us to question popularly held beliefs about the definition of "good science." The traditional view of science holds that truths revealed by nature are available for skilled scientists to discover and add to the body of received knowledge through repeated, careful experimentation. Science, under this reading, is "good" or "bad" according to the fidelity with which it represents what is actually happening in nature. Scientists (and only scientists) are believed capable of policing the boundary between good and bad science; the instrument they use for this purpose is the scientific method, which centers on testing and replication, and which — when properly deployed — is thought to be a virtually foolproof device for weeding out error. Only replicated results, according to standard doctrine, are worthy of acceptance within the established canons of science.

From the social constructivist vantage point, however, the creation of scientific knowledge is much less objective and methodologically watertight. "Truth" emerges not because nature, when interrogated by the scientific method, unambiguously reveals the answers, but because discipline-based scientists agree, through complex processes of negotiation and compromise, how they should choose among different possible readings of observations and experiments. Determinations concerning the goodness or badness of alternative scientific methods, theories and claims are similarly subject to negotiation among groups of experts.

The constructivist argument further holds that science, under appropriate circumstances, can be "deconstructed," that is, broken down into the conflicting subjective assumptions and interpretations from which the claims in question were initially formulated. When such disintegration occurs, consensus vanishes, to be replaced by conflicting accounts of what the evidence means and how persuasive it is. In the process of deconstruction, scientists freely attack each other's claims on personal and subjective grounds ("I simply don't trust his/her results"), as well as on grounds related to their opponent's theories and experimental methods ("I don't consider that approach to be scientifically valid").

**Table 1**

| | *Regulatory Science* | *Research Science* |
|---|---|---|
| Goals | "Truths" relevant to policy | "Truths" of originality and significance |
| Institutions | Government<br>Industry | Universities |
| Products | Studies and data analyses, often unpublished | Published papers |
| Incentives | Compliance with legal requirements | Professional recognition and advancement |
| Time-frame | Statutory timetables<br>Political pressure | Open-ended |
| Options | Acceptance of evidence<br>Rejection of evidence<br>Waiting for more data | Acceptance of evidence<br>Rejection of evidence |
| Accountability | | |
| Institutions | Congress<br>Courts<br>Media | Professional peers |
| Procedures | Audits and site visits<br>Regulatory peer review<br>Judicial review<br>Legislative oversight | Peer review, formal and informal |
| Standards | Absence of fraud or misrepresentation<br>Conformity to approved protocols and agency guidelines<br>Legal tests of sufficiency (e.g., substantial evidence, preponderance of evidence) | Absence of fraud or misrepresentation<br>Conformity to methods accepted by peer scientists<br>Statistical significance |

One does not have to believe rigidly in the constructivist account of science or adopt the most radical form of ontological skepticism to conclude that regulatory science is particularly susceptible to divergent, socially conditioned interpretations. Academic research science, as practiced in university laboratories, tends to be conducted in

environments of reasonably strong consensus, governed by established paradigms and relatively uncontested methodological and quality control standards. In regulatory science, by contrast,[7] standards for assessing quality tend to be more fluid, controversial and sensitive to political factors. Important studies often straddle disciplinary boundaries, so that clearcut assessment standards are hard to identify. Further, regulatory science is often constrained by strict time limitations that impede scientific consensus-building. At the same time, the stakes are so much higher in regulatory than in research science that different interests groups have incentives to press for divergent, politically congenial interpretations of the available facts. Table I summarizes these contrasts.

In scientific arenas with uncertain facts, underdeveloped theoretical paradigms, inconsistent and contested study methods, and politically salient outcomes, it is hardly surprising that experts' readings of the data will incorporate subjective biases, such as varying degrees of risk aversiveness or willingness to tolerate Type I versus Type II statistical errors. Many detailed studies of expert opinion in the area of carcinogen risk assessment confirm that scientific and policy judgments intermingle when scientists are confronted with issues labeled as "trans-science," "science policy" or "at the frontiers of scientific knowledge."[8]

These properties of regulatory science help explain why controversies about scientific issues arise so frequently and are pursued so stubbornly in the regulatory process.[9] On the one hand, our regulatory laws mandate a culture where regulators and interest groups alike seek to resolve their differences through appeals to objective knowledge. On the other hand, decisions are often based on adversarial proceedings that highlight the scientific differences among participants and impede negotiation and consensus-formation. Decision makers compelled to choose between conflicting but well-articulated scientific claims therefore run the risk of appearing biased or inconsistent. This

7 It should be understood, of course, that the terms "regulatory science" and "research science" as used here are ideal types; in reality, science can seldom be neatly boxed into either category.

8 *See, e.g.*, MARK E. RUSHEFSKY, MAKING CANCER POLICY (1986).

9 SHEILA JASANOFF, RISK MANAGEMENT AND POLITICAL CULTURE (1986).

point, noted as early as 1977 in a National Academy of Sciences (NAS)[10] study of EPA decisionmaking, has since been confirmed in numerous case studies of regulatory proceedings.

## Four Structures of Scientific Assessment

Practices and traditions for building a scientific record differ from agency to agency in the federal government. In regulatory programs where consultation with outside experts is legally mandated, for example, the governing statute may specify which decisions should be subjected to external review and at what stage in the decisionmaking process. More generally, the consideration of technical evidence is governed by congressionally imposed procedural restrictions, which in most cases are substantially more elaborate than the basic notice and comment provisions of the Administrative Procedure Act.

Although no two agencies structure their processes for scientific review exactly alike, some of the crucial differences among agencies can be captured in the following two-by-two matrix.

| *Assessor* | *"Legislative" Process* | *"Adjudicatory" Process* |
|---|---|---|
| Scientists Assess Risk Information | 1 | 2 |
| Agency Assesses Risk Information | 3 | 4 |

One dimension indicates which of two decision makers — the agency staff or outside experts — does the initial risk assessment. The second refers to procedural form — legislative (informal) or trial-type (formal) — used to definitively interpret the evidence. Proceedings belonging in boxes 1 and 2 are perhaps best illustrated by FDA's programs for reviewing drugs and food additives. The agency initially grants wide powers to its outside experts. They may be asked to evaluate the strength and quality of the scientific literature pertaining to risk, as well as to determine whether there is sufficient evidence of risk,

10 NATIONAL ACADEMY OF SCIENCES, 2 DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY 48 (1977).

whether the risk is significant, and, occasionally, how the agency should act to control the risk. For proceedings in boxes 3 and 4, by contrast, the initial data evaluation and risk assessment are carried out by the agency's in-house staff and are presented for validation to an external scientific committee, functionally analogous to a panel of expert judges. Examples include EPA's review processes for ambient air quality standards under the Clean Air Act and for pesticide decisions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Proceedings in boxes 2 and 4 are most court-like in form, with box 4 corresponding most closely to the science court model.

The theory of social constructivism implies that processes fostering negotiation rather than confrontation (hence, those in boxes 1 and 3) are most likely to lead to acceptable consensus positions on scientific issues. According to this view, parties who participate in negotiating competing claims will sooner converge toward a shared cognitive position than those who remain outside the negotiation process. Common readings of contested evidence are less likely to develop in adversarial settings, particularly when scientific debate is polarized along political lines, so that participants have economic or ideological stakes in deconstructing each other's claims. These predictions appear to find support in empirical research, as illustrated below.

### *Sulfites*

A review of the health risks of sulfiting agents (compounds used in food preparation to prevent discoloration) sponsored by FDA illustrates how both regulatory science and regulatory policy issues were satisfactorily resolved in a proceeding that combined risk assessment by an expert panel with informal procedures for soliciting public input. Review was triggered in this case by reports in the medical literature of acute allergic responses to sulfites in food, including a number of fatalities. FDA contracted with the Federation of American Societies for Experimental Biology (FASEB) to analyze the medical reports and determine how sulfites should be classified in terms of risk to public health. To carry out these tasks, FASEB appointed an ad hoc panel of experts, almost all of whom had previously advised FDA on the issue of sulfite sensitivity.

The expert panel concluded its initial review of the literature with a draft report stating that there was cause for concern about sensitive individuals (e.g., asthmatics) exposed to sulfites and that these concerns could best be addressed by means of warning labels in restaurants and markets offering sulfite-treated foods. The panel then held a public meeting at which evidence was taken from a variety of sources: consumer groups, representatives of the food industry and scientists working on sulfite reactions. The testimony presented at this meeting led the panel to reaffirm its conclusion that sulfites were safe at allowed doses for the general population, but that they presented a risk of "unpredictable severity" for specially sensitive individuals. However, the panel reversed itself on the issue of warning labels and advised FDA that labeling alone would not adequately protect sulfite sensitive persons in all exposure contexts. Sulfite use, the panel recommended, should be banned for some categories of foodstuffs, most notably fresh produce on salad bars. FDA went along with this recommendation in its final regulatory package on sulfites.

In this case, the independent panel's expertise bolstered FDA's judgment that sulfites posed a health threat deserving of regulatory attention, even though scientific evidence about the nature and magnitude of risk was by no means conclusive. At the same time, the open public meeting held by the panel gave participants of varied interests and affiliations the chance to comment meaningfully on the nontechnical aspects of the decisionmaking process. Importantly, the panel served as a forum for mediating among different viewpoints on who should be protected and at what cost, rather than as a technical judiciary charged with finding the single scientifically "correct" answer. The panel's success can be gauged from the fact that FDA's subsequent imposition of a partial ban on sulfites aroused no serious opposition or criticism.

*Aspartame*

The Public Board of Inquiry (PBOI) convened by FDA to review the safety of the artificial sweetener aspartame illustrates how an expert panel can fall short of offering useful policy advice by too strictly

insulating scientific fact-finding from the subsequent regulatory decision. In this case, a panel of three scientist "judges" heard evidence from numerous scientist "witnesses" holding different views about the safety of aspartame. All the questioning at the hearing was carried out by scientists rather than lawyers. Some commentators have described the proceeding as a kind of "science court,"[11] but others have noted that it was more like a scientific seminar, because there was no advocacy of particular policy outcomes.[12] Unlike a court decision, moreover, the PBOI's judgments about the scientific data were only advisory; they were not regarded as binding by the agency.

Consistent with the empirical literature on such expert inquiries, the PBOI was fairly successful in pinpointing areas of scientific disagreement and getting alternative views of the data out into the open. It was, however, less successful as a mechanism for building an authoritative scientific rationale to guide policy action. Efforts to showcase the PBOI as an objective, scientific proceeding proved controversial, as critics pointed to possible disciplinary and institutional biases on the panel. Lawyers deplored the ambiguous legal status of the PBOI's findings, as well as the panel's failure to adhere to such basic norms of legal decisionmaking as providing citations to the record in its final decision. Finally, although the PBOI concluded that more testing was needed to determine whether aspartame caused brain tumors, FDA overrode the board's scientific opinion and approved the compound for certain tabletop uses without waiting for additional evidence. The PBOI apparently did not damage FDA's credibility, but it would be difficult to conclude that the proceeding substantially improved the agency's scientific assessment of aspartame. Indeed, it is arguable that decisionmaking proceeded in relatively untroubled fashion precisely because FDA felt free to make its policy decision unconstrained by the PBOI's expert judgment.

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11 Vincent Brannigan, *The First FDA Public Board of Inquiry: The Aspartame Case*, in LAW AND SCIENCE IN COLLABORATION (J.D. Nyhart & Milton M. Carrow eds. 1983).

12 Sidney A.Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 1986 DUKE L.J. 288-45.

*Ozone*

The ozone case shows how scientific review in one EPA program became more effective when the agency shifted from an adversarial to a negotiated approach and, at the same time, stopped insisting on a rigid separation of science from policy. EPA undertook to review the primary national ambient air quality standard (NAAQS) for ozone in the late 1970's. The agency's official advisory panel, a precursor to the current Science Advisory Board (SAB), found fault with the scientific data and arguments underlying the proposed standard. EPA thereupon sought to bypass the SAB committee by seeking advice from a separate, more sympathetic committee constituted under the leadership of Dr. Carl Shy, a "pro-health" scientist. To justify this irregular and ad hoc procedure, EPA argued that certain legally mandated determinations (e.g., the meaning of "adverse health effect") were matters of policy that could be decided by the agency without review by the SAB. These attempts to increase its jurisdiction over decisions at the boundary of science and policy exposed EPA to a lawsuit,[13] as well as to criticism from both the scientific and policy analytic communities.[14]

In a subsequent review of the ozone standard, EPA adopted a significantly more conciliatory attitude to its Clean Air Scientific Advisory Committee (CASAC). The review process was modified to allow the committee to interact at least twice with the agency staff: once over the statutorily required "criteria document" and once over the "staff paper" containing the rationale for the proposed standard. EPA, moreover, stopped insisting that the committee's jurisdiction was limited exclusively to science. In a more conciliatory spirit, the agency permitted the panel to discuss borderline questions that had previously been designated as (science) policy. Specifically, CASAC addressed both the definition of "adverse health effect" and the choice of a risk assessment methodology.

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13 American Petroleum Institute v. Costle, 665 F.2d 1176 (D.C.Cir. 1981).

14 For an impressively detailed criticism of EPA's decision making in this case, *see* R. SHEP MELNICK, REGULATION AND THE COURTS (1983).

As one pay-off from this strategy, EPA gained CASAC's support for some controversial methodological and interpretative decisions, including the contested approach to risk assessment that had so troubled the SAB panelists. Of course, the agency had in the interim substantially refined its risk assessment procedures and was on stronger technical ground than in the first ozone review. But transcripts of CASAC meetings suggest that discussing the issues in a non-adversarial negotiating environment was also an important factor in overcoming the skepticism of some committee members and in gaining the committee's eventual backing for the agency's risk assessment strategy.

*Daminozide (Alar)*

The Alar case, by contrast, supports the view that confrontational advisory procedures, with outside scientists cast in a judicial role, are poorly suited to building a workable consensus on regulatory science. EPA's Office of Pesticide Programs (OPP) carried out a review and risk assessment of daminozide (trade named Alar) and its breakdown product UDMH to determine whether this widely used plant growth regulator was safe for use. Based on available bioassay results, OPP concluded that Alar posed a significant risk of human cancer and should be promptly withdrawn from the market. The agency's Scientific Advisory Panel (SAP), however, came to quite a different conclusion. In the SAP's judgment, all of the animal studies relied upon by OPP were flawed and should not have been used for quantitative risk assessment.[15] Since these views effectively ruled out immediate action on Alar, EPA felt its only recourse was to ask Uniroyal, Alar's manufacturer, to carry out additional studies on the substance's carcinogenicity. Environmental groups went to court claiming that EPA should not have relied on the panel and should have regulated Alar on the evidence already available, but their plea was denied on procedural grounds.[16]

[15] These proceedings are discussed in greater detail in Sheila Jasanoff, *EPA's Regulation of Daminozide: Unscrambling the Messages of Risk*, 12 SCIENCE, TECHNOLOGY AND HUMAN VALUES 116 (1987).

[16] Nader v. EPA, 859 F.2d 747 (9th Cir. 1988).

When Uniroyal's tests apparently confirmed the earlier scientific findings of carcinogenicity, EPA encountered much negative publicity for its handling of the case. A perturbing risk assessment of Alar produced by the Natural Resources Defense Council (NRDC) caught national attention, even though it was based in part on studies previously discredited by the SAP. Under growing consumer pressure, Uniroyal "voluntarily" withdrew the product from the market.

In this case, peer review by the SAP initially prevented EPA from proceeding on the basis of problematic animal studies. However, the adversarial flavor of the Alar review fed suspicions among environmentalists that the SAP members were allied with (or "captured" by) industry. In a politically polarized environment, NRDC's efforts to seize the scientific initiative and to project its own assessment of risk proved highly successful. In the end, the public attached greater weight to NRDC's seemingly more disinterested expertise than to the alternative risk assessment prepared by EPA and endorsed by the SAP.

## Improving the Fit between Science and Policy

These four regulatory science controversies suggest that the legitimacy of scientific assessments in a policy setting can be enhanced through procedures that stress negotiation and compromise, rather than adversarial conflict, among interested parties. The constructivist viewpoint implies, in particular, that claims concerning regulatory science can be made more credible to both lay and expert audiences if the independent scientific community engages with other interests — including government scientists — in a process of mutual accommodation. When outside scientists are poised adversarially in relation to the agency, rifts may develop between their respective interpretation of the data, with damage to the credibility of both sides.

At the same time, a scientific assessment process that is symbolically insulated from the appearance of politics may play a critically important role in certifying that evidence conforms to standards judged acceptable by the scientific community. Controversies over regulatory science often turn on the issue of when the evidence should be deemed strong enough

to justify regulatory action. Given the uncertainties of the data, it is almost always possible for skeptics to argue that more research or "better" science would clarify policy choices. Thus, decisions to proceed on the basis of available evidence generally involve a trade-off between more data and quicker action, or, more crudely, science and safety. This is an area where an independent scientific process can usefully shore up an agency's judgment.

The scientific controversies of the 1970's arose, in part, because regulatory agencies failed to acknowledge the need for some role separation between science and policy. They acted on the basis of internal scientific analyses — often labeled (science) policy — without securing support from scientists outside government. The Alar controversy illustrates the opposite dynamic, with the scientific assessment in effect swallowing up the policy-maker's independent role. The result was to taint the advisory committee as too pro-industry, because it accepted the views of Uniroyal's experts with too little apparent regard for EPA's contrary analysis.

The foregoing observations lead to several general recommendations for achieving a better fit between science and policy in regulatory decision making:

*Forum Design.* An appropriate choice of institutional forum is an essential step in facilitating negotiation among the interests (both scientific and non-scientific) that have a stake in the interpretation of science. One approach is to create multipartite bodies that are capable, simultaneously, of negotiating differences over "facts" and values. But achieving a harmonious political balance on committees that are perceived as scientific may not always be feasible. The scientific community, for instance, vigorously rejected a proposal to place on EPA's Science Advisory Board designated representatives of industry, environmental groups and other political interests.[17] Proposals to make expert groups openly political should be approached with caution on theoretical grounds as well. Particularly in the U.S. regulatory context, an expert committee's cardinal function is to certify that the science used

[17] Nicholas A. Ashford, *Advisory Committees in OSHA and EPA: Their Use in Regulatory Decisionmaking*, 9 SCI. TECH. & HUM. VALUES 72 (1984).

in regulatory decisions is legitimate. Its capacity to deliver this message forcefully may be weakened if its scientific credentials appear to be compromised by political ties.

An alternative approach, which has been successfully used in selecting SAB members at EPA, is to ensure informally that experts appointed to an assessment body span a representative range of scientific and philosophical positions. This option is consistent with the constructivist viewpoint, since it acknowledges that scientists are not value-free. The tradeoff is that it gives the appointing agency considerable latitude in selecting experts and depends for its success on the experience and integrity of the agency's administrative staff.

*Process Design.* It emerges from the foregoing discussion that advisory committee proceedings should be structured, wherever possible, as occasions for multilateral exchange, with opportunities for give-and-take between the experts, the agency and other interested participants. In rule making as in litigation, adversarial proceedings polarize and harden differences of opinion, narrow the range of views presented and hinder negotiation and compromise. These negative consequences are especially difficult to avoid when scientific advice is incorporated by law into a fundamentally adjudicatory process, as in the case of FIFRA proceedings. Agencies other than EPA, however, generally retain the discretion to structure their interactions with the scientific community in formats of their own selection. For example, FDA voluntarily decided to assess aspartame by means of the court-like Public Board of Inquiry. A proposal in the mid-1970's that agencies should use scientists rather than lawyers to cross-examine experts was similarly premised on a belief that science should be separated from policy and that adversarial procedures were a desirable means of establishing scientific "truth."[18] Again, both theoretical and empirical explorations of regulatory science suggest that such initiatives are ill advised.

The timing of scientific assessment by outside experts is another issue that merits consideration in designing appropriate rulemaking

[18] James C. Miller III, *Regulation and Experts: A Modest Proposal*, Regulation, Nov./Dec., 1977, at 36.

processes. In general, the more delayed the onset of consultation, the greater is the potential for divergences to develop between agencies and their expert advisers — and, consequently, for disputes to arise over the "correct" reading of regulatory science. Processes that allow for repeated consultation between agencies and reviewing bodies (as in the review of EPA's ozone standard) would guard against such drift and would be most in keeping with the negotiated model of science. Such proceedings, however, are expensive and hence may not be cost-effective for most regulatory programs.

Where repeated consultation is not feasible, using the scientific advisory process to arrive at the initial determination of risk (as in FDA's sulfite and aspartame proceedings) may provide a safety valve against subsequent controversy. This approach, however, may be legally foreclosed if it is inconsistent with an agency's statutory mandates concerning the timing of expert review. Also, as a practical matter, asking advisory committees to review the scientific literature and perform a risk assessment may be realistic only when the scientific issues are fairly limited in scope and do not cut across many disciplinary boundaries.

*Judicial Review.* Scientific review, as noted above, can help certify that inferences drawn by regulatory agencies are within the range of choices deemed acceptable by the relevant expert community. Another way of stating this point is to say that review by outside experts helps confirm that regulatory decisions are substantively rational. In this respect, scientific review performs a function normally assigned to the courts in U.S. administrative law. Evidence from empirical studies of decision making indicate, for instance, that scientific reviewers ask agencies many of the same questions that courts traditionally have asked pursuant to the "hard look" doctrine: Is the analysis balanced? Does it take account of all the relevant data? Do the conclusions follow rationally from the evidence? Is the analysis clear, coherent and presented in an understandable manner?[19] By virtue of their specialized training and experience, scientific reviewers are likely to be more

[19] *See generally* SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS (1990).

effective than judges in evaluating agency responses to such questions.

There is little evidence that courts, for their part, clearly understand the role and limits of scientific review or have begun to think about the appropriate relationship between review by expert panels and judicial review. One reason for this state of affairs is that only a handful of lawsuits in the area of health, safety and environmental regulation have specifically focused on the adequacy of agency dealings with expert committees. When this issue is raised, experience to date suggests that courts may be more inclined to evade it than to address it. Thus, in *API v. Costle* (the ozone case), the D.C. Circuit found it unnecessary to consider whether EPA's consultation with the Shy Panel violated the Federal Advisory Committee Act,[20] since the agency did not follow the panel's recommendations in promulgating the final ozone standard. As to EPA's failure to consult fully with the SAB in the same case, the court held that this oversight, while serious, was insufficient by itself to invalidate a standard that otherwise appeared to be adequately supported by the record. In *Nader v. EPA* (the Alar case), the plaintiff environmental groups charged EPA with an "arbitrary and capricious" decision to follow the SAP's restraining advice, when the agency, in their view, had a legally sufficient basis for regulating Alar. The Ninth Circuit, however, ruled against the plaintiffs on the ground that they had failed to raise these claims in timely fashion before the agency.

Since conscientious scientific review overlaps functionally with substantive judicial review, courts should be especially reluctant to intervene in cases where it appears that an expert panel has forced the agency to take a "hard look" at the scientific record. However, despite their functional similarities, scientific review and judicial review are not in the final analysis equivalent processes. No matter what an expert panel says about an agency's analysis of science, courts have an independent duty to ensure that regulatory decisions comply with the law. In the exercise of this prerogative, courts may on occasion mandate regulatory action even if an expert panel counsels the opposite.[21] More

[20] 5 U.S.C. App (1988), Pub. L. 92–463, 86 Stat. 770 (1972).

[21] This is arguably what happened in Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987). In that case, FDA consulted with a scientific advisory panel to

typically, however, courts should expect to play an assertive role in reviewing cases where agencies and advisory committees disagree in their readings of the scientific record or when there is evidence of impropriety in soliciting scientific advice.

## Conclusion

More than two decades of experience with science-intensive policy-making have established beyond doubt that regulatory agencies need the independent scientific community to validate their own exercises of expert judgment. Contrary to some early expectations, however, the format of the science court has not proved to be especially helpful in structuring the interactions between governmental and independent experts. The technical issues that arouse greatest controversy in regulatory settings lie in a grey zone between science and policy or facts and values. Typically, there is no single right way to iron out the multiple ambiguities in the regulatory record; decisions about the "science" almost invariably are complex constructs, incorporating elements of science as well as society. Both scientists and policy-makers, therefore, must participate in the process of resolving disputes over regulatory science, and I have suggested that it is important for symbolic reasons to keep the scientists' role institutionally separate from that of the policy-maker. Aiming for the kind of rigid cognitive separation that underlies the science court idea, however, is bound to be counterproductive, as is the insistence on adversarial modes of fact-finding. In regulatory science, as most areas of contested human activity, solutions are more likely to emerge from negotiation and compromise than from bipolar, head-to-head conflict.

confirm its view that certain color additives presented a de minimis risk of human cancer and hence, implicitly, should not be regulated under the Delaney clause of the Federal Food, Drug, and Cosmetic Act. The court held, in effect, that the panel's scientific advice was immaterial to the legal outcome, since the statute unambiguously called for a ban on color additives shown to induce cancer in animals.