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Procedural Choices in Regulatory Science*

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ABSTRACT. Policymakers have long assumed that scientific inputs to regulatory decisions (facts) should be insulated as far as possible from political and policy considerations (values). Some have even recommended a complete institutional separation between scientific and political decisionmaking on the model of the science court. Drawing on research in the social studies of science, this paper suggests that such separatist models fail to address important differences between regulatory science and research science. Regulatory science, which provides the basis for policy, routinely operates with different goals and priorities and under different institutional and temporal constraints from science done in academic settings and without implications for policy. Four brief case studies are presented to underscore the need for negotiations between science and policy in making regulatory decisions. The paper concludes that adversarial or trial-type approaches are generally less effective than processes that promote negotiation among competing interpretations of regulatory science. This finding, in turn, has implications that should be factored into the institutional and procedural design of scientific advice in the regulatory process.

Introduction

Over the past twenty-five years, federal regulatory agencies have emerged as a critically important locus for scientific fact-finding and for adjudicating controversies about science. In implementing programs of health, safety, and environmental regulation, agency experts must review and assess the

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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 legaiiy mandated peer review — have received considerable attention in discussions of regulatory reform;[2] proposals to strengthen peer review procedures in federal agency decisionmaking were a prominent part of the Republican Party's legislative agenda following the 1994 election. The idea that scientific 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, involving scientists as both advocates and fact-finders, would be the most appropriate procedural format for resolving the technical conflicts that arise in the course of regulation.[4]

My aim in this paper is to assess how procedural choices influence the use of science in regulatory decisionmaking. Looking at four well-established approaches to the evaluation of science for governmental purposes, I will argue that the adversarial procedures employed by courts and court-like agencies are generally less effective in achieving regulatory objectives than procedures that are more sensitive to the uncertainties and indeterminate boundaries 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 discuss some of the advantages agencies have gained by shifting away from more court-like proceedings toward less adversarial procedures for scientific deliberation.

The Characteristics of Regulatory Science

To understand why some approaches to evaluating science work better than others in regulatory settings, we should begin with an inquiry into the special properties of the science that forms the basis for public decisions. How, specifically, should we characterize science used for regulatory purposes (hereafter "regulatory science") in the light of currently accepted accounts

of the nature of scientific 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. Social constraints on the production of scientific knowledge include, most obviously, the theoretical and methodological limitations imposed by prevailing research paradigms in a given discipline or historical period. More controversially, however, scientific claims also tend 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 a number of sources, including the study of scientific controversies, ethnographic studies of laboratories, and historical investigations of the rise and fall of particular scientific theories or research schools.[6]

Proponents of the theory of "political capture" have attributed scientific disputes that arise in policymaking to the intentional manipulation of facts by political interests. By contrast, advocates of social construction deny that ideological differences among experts are the sole cause of variations in the interpretation of data. Social studies of science suggest instead that expert disputes can arise out of "honest" philosophical 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. Scientists' rhetoric often diverges from their practice. Thus, scientists committed to maintaining disciplinary rigor may publicly insist that only contemporary controls be used in conducting bioassays or epidemiological studies; at the same time, practices within the discipline may vary greatly, showing that scientists routinely use both historical and contemporaneous controls.[7]

These findings have important implications for science in the policy process, for they lead us to question popularly held beliefs about the concept 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 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 a virtually foolproof device for weeding out error. Only replicated results, according to standard doctrine, are worthy of acceptance within established canons of science.

From the social constructivist vantage point, however, the creation of scientific knowledge is much less objective and methodologically controlled.

"Truth" emerges not because nature, aided by the scientific method, unambiguously reveals the answers, but because scientists, through complex processes of negotiation and compromise, agree how to 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.

The constructivist argument further holds that science, under appropriate circumstances, can be "deconstructed," that is, broken down into the conflicting subjective assumptions and assertions 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 really means. 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 opponents' theories and experimental methods. It is not necessary to believe unswervingly in the constructivist account of science or to adopt a radical form of ontological skepticism to conclude that regulatory science is particularly susceptible to divergent, socially conditioned interpretations. Thus, research science, as practiced in university laboratories, tends to be conducted in environments of relative consensus, governed by established paradigms and relatively clear methodological and quality control standards. In regulatory science, by contrast, standards for assessing quality tend to be more fluid, controversial, and subject to political considerations. Further, regulatory science is more often bound by strict time limitations, which impede scientific consensus-building; the stakes, too, are often higher in regulatory than in research science, so that different interest groups have incentives to press for divergent, politically congenial interpretations of the available facts. Table 1 summarizes these contrasts. (It should be understood, of course, that the terms "regulatory science" and "research science" are here used as ideal types; in reality, scientific studies and results can seldom be neatly boxed into either category.)

In a scientific arena where facts are uncertain, theoretical paradigms are underdeveloped, study methods are inconsistent and contested, and outcomes are politically salient, 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. Numerous detailed studies of expert opinion in the area of carcinogen risk assessment have confirmed that scientific and policy judgments do indeed intermingle when scientists are confronted with issues variously labeled as "trans-science," "science policy" or "at the frontiers of scientific knowledge."[8]

These properties of regulatory science help explain why controversies about science arise so frequently and are pursued so stubbornly in the regulatory process.[9] On the one hand, our laws mandate a regulatory culture of high public accountability, where regulators and interest groups alike seek to resolve their differences through appeals to objective knowledge. On the

TABLE 1.

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

other hand, decisions are often based on adversarial proceedings, which highlight the scientific differences among participants and impede negotiation and consensus-formation. Decisionmakers compelled to choose between conflicting but well-articulated scientific claims therefore run the risk of appearing biased or inconsistent. This point, noted as early as 1977 in a study of EPA decisionmaking by the National Academy of Sciences (NAS),[10] has since been confirmed in numerous case studies of regulatory proceedings.

Four Approaches to 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 that are in most cases 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. One dimension indicates which of two decisionmakers — the agency staff or a body of outside experts — carries out the initial risk assessment. The second refers to the form of the procedural form — legislative (informal) or trial-type (formal) — used to establish a definitive interpretation of the evidence. Proceedings belonging in boxes 1 and 2 are perhaps best illustrated by FDA's programs for reviewing drugs and food additives.

	"Legislative" Process	"Adjudicatory" Process
Scientists Assess Risk Information	1	2
Agency Assesses Risk Information	3	4

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, 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 model of the science court.

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 insist simply on challenging rival interpretations of the data. Common readings of contested evidence are least likely to develop in adversarial settings

in which scientific debate is polarized along political lines and where 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 exposed to sulfites (for example, asthmatics), 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 a 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 "correct" answer to a disputed factual question. 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" who held different views about the safety of aspartame. All the questioning at the hearing was carried out by scientists rather than lawyers. Commentators have described the proceeding as a kind of "science court," but others have noted that it was more like a scientific seminar, because there was no advocacy of particular policy outcomes.[11] Unlike a court decision, however, 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 readings 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.

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 1970s. 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 (for example, the meaning of "adverse health effect") were matters of policy that could be decided by the agency without review by SAB. These attempts to increase its jurisdiction over decisions at the boundary of science and policy exposed EPA to a lawsuit,[12] as well as to criticism from both the scientific and policy analytic communities.[13]

In a subsequent review of the ozone standard, EPA adopted a significantly more cooperative 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.

As one pay-off from this strategy, EPA gained CASAC's support for some controversial methodological and interpretive 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 much stronger scientific 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. On the basis of 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 SAP's judgment, the animal studies relied upon by OPP were flawed and should not have been used for quantitative risk assessment.[14] Since these views effectively ruled out immediate regulatory action, 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 regulate Alar on the evidence already available, but a court denied their plea on procedural grounds.[15]

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 discredited by the SAP reviewers. Under growing pressure from the media and consumers, Uniroyal "voluntarily" withdrew the product from the market, thereby ending the scientific controversy.

In this case, peer review by 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 SAP.

Spanning Science and Policy

These four controversies about regulatory science 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. A well-designed scientific assessment process should facilitate the resolution of politically charged differences in the interpretation of data, but it must also remain insulated from the appearance of politics in order to play an effective role in certifying that its findings conform to standards judged acceptable by the scientific community. Controversies over regulatory science often turn on the issue of when evidence of risk should be deemed strong enough to justify regulatory action. Given the uncertainties of the data and the underlying models, skeptics can almost always 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, between science and safety. This is an area where an independent scientific process can usefully shore up an agency's judgment.

Many scientific controversies of the 1970s and 1980s arose because regulatory agencies failed to acknowledge the need for clear role separation between science and policy. Administrators acted on the basis of scientific analyses produced within their own agencies — often labeled (science) policy — without securing support from scientists outside government. The Alar controversy illustrated the opposite dynamic; here, a scientific advisory body in effect substituted its science policy judgments for EPA's, thus swallowing up the policymaker's independent role. In the end the advisory committee was tainted as too pro-industry, because it accepted the views of Uniroyal's experts with 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 decisionmaking.

Defining the science-policy boundary. Case studies of scientific deliberation associated with regulation underscore the fluidity of the boundary between the "scientific" and "policy" components of decisionmaking. Judgments that seem purely scientific on the surface, such as choices of research design, are influenced by policy concerns ranging from the costs of data gathering to concerns about who should bear the burden of proof when data are uncertain.[16] Equally, however, key policy choices, including the interpretation of statutory terms such as "adverse health effects," may demand inputs from the medical and scientific research communities concerning the present state of knowledge in their fields. It is not surprising then that attempts to make *a priori* determinations of where science ends and policy begins in regulatory science — whether on the basis of "universal" characteristics of the scientific method or on the basis of decisions to separate risk assessment from risk management — have encountered repeated obstacles.

With the maturation of regulatory science as a domain of combined scientific and policy expertise, there is growing recognition that the scientific advisory process offers an instrument for delineating, case by case, where the boundary between science and policy may reasonably be drawn in particular instances of decisionmaking. The National Research Council, for example, has called attention in several recent reports to the need for integrating scientific and public policy concerns at each step of decisionmaking, without, of course, endangering the integrity of scientific assessment.[17] Recently, too, a "Reinvention Committee" constituted by EPA's Science Advisory Board acknowledged SAB's central role in helping the agency to span science and policy. In deliberations held during 1994, committee members indicated that they did not wish SAB to voice (or be seen as voicing) its own policy preferences, but they admitted the need for SAB to comment on the policy implications of regulatory science. The committee also concluded that SAB's mission statement should address the problems of turf and responsibility at the borderline of science and policy.[18]

Forum design. If negotiation among the affected interests (both scientific and non-scientific) is an essential step in the interpretation of regulatory

science, then the choice of an appropriate institutional forum emerges as an important element of good decisionmaking. 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.[19] 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 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 the selection of 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 rulemaking 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 a court-like Public Board of Inquiry. A proposal in the mid-1970s that agencies should use scientists rather than lawyers to cross-examine experts was similarly premised on an acceptance of adversarial procedures as a desirable means of establishing scientific "truth."[20] 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 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 communities. 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 formally assigned to the courts in U.S. administrative law. Evidence from empirical studies of decisionmaking indicate, for instance, that scientific reviewers ask agencies many of the same questions that courts traditionally have asked pursuant to the "hard look" doctrine of judicial review: 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?[21] By virtue of their specialized training and experience, scientific reviewers are likely to be more 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 Court of Appeals found it unnecessary to consider whether EPA's consultation with the Shy Panel violated the Federal Advisory Committee Act, 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 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. In *Nader v. EPA* (the Alar case), the plaintiff environmental groups charged EPA with an "arbitrary and capricious" decision to follow 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 in which it appears that an expert panel has forced the agency to take a "hard look" at the scientific record. Pursuant to several Supreme Court decisions of the past two decades, federal courts have in any case retreated from their once aggressive supervision of administrative decisionmaking.[22] Yet, 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.[23] More typically, however, courts should expect to play an assertive reviewing role in cases where an agency and its advisory committee 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 policymaking 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 adversarial 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 social policy. 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 reasons of political legitimacy, to keep the scientist's role institutionally separate from the policymaker's. Aiming for the kind of rigid cognitive separation that underlies the science court idea, however, is bound to be counterproductive. 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.

Notes

1. See, for example, Kristin Shrader-Frechette, "Risk Estimation and Expert Judgment: The Case of Yucca Mountain," *Risk — Issues in Health and Safety* 3 (1992), pp. 283–315.
2. National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (Washington, DC: National Academy Press, 1983); American Chemical Society and The Conservation Foundation, "Issues in Peer Review of the Scientific Basis for Regulatory Decisions," Wash-

ington, DC, November 1985; Thomas S. Burack, "Of Reliable Science: Scientific Peer Review, Federal Regulatory Agencies, and the Courts," *Virginia Journal of Natural Resources Law* 7 (1987), pp. 27–110.

3. See, for example, Halina Szejnwald Brown and Robert L. Goble, "The Role of Scientists in Risk Assessment, *Risk — Issues in Health and Safety* 1 (1990), pp. 283–311.
4. See, for instance, Task Force of the Presidential Advisory Group on Anticipated Advances in Science and Technology, "The Science Court Experiment: An Interim Report," *Science* 193 (1976), pp. 652–656. See also Alvin Weinberg, "Science and Trans-Science," *Minerva* 10 (1972), pp. 209–222 (suggesting that procedures borrowed from the law are best suited to resolving trans-scientific questions).
5. See, for example, Karin D. Knorr-Cetina and Michael Mulkay, eds., *Science Observed* (London: Sage 1983). On the social construction of risk, see Branden Johnson and Vincent Covello, eds., *The Social and Cultural Construction of Risk* (Dordrecht, Netherlands: Reidel, 1987).
6. Major works in these areas include Dorothy Nelkin, ed., *Controversy*, 2d ed., (Beverly Hills, CA: Sage, 1984); Bruno Latour and Steve Woolgar, *Laboratory Life* (Princeton, NJ: Princeton University Press, 1986); Thomas S. Kuhn, *The Structure of Scientific Revolutions*, 2d ed. (Chicago: University of Chicago Press, 1970).
7. For some examples of such discrepancies between idealized and actual accounts of scientific practice, see Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, MA: Harvard University Press, 1990), pp. 26–29, 74–76.
8. See, for example, Mark E. Rushefsky, *Making Cancer Policy* (New York: SUNY Press, 1986).
9. Sheila Jasanoff, *Risk Management and Political Culture* (New York: Russell Sage Foundation, 1986).
10. National Academy of Sciences, *Decision Making in the Environmental Protection Agency*, Vol. II (Washington, DC: National Academy Press, 1977), p. 48.
11. Vincent Brannigan, "The First FDA Public Board of Inquiry: The Aspartame Case," in J.D. Nyhart and Milton M. Carrow, *Law and Science in Collaboration* (Lexington, MA: Lexington Books, 1983), pp. 165–202; Sidney A. Shapiro, "Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry," *Duke Law Journal* (1986), pp. 288–245.
12. *American Petroleum Institute (API) v. Costle*, 665 F.2d 1176 (D.C.Cir. 1981).
13. For an impressively detailed criticism of EPA's decisionmaking in this case, see R. Shep Melnick, *Regulation and the Courts* (Washington, DC: Brookings Institution, 1983).
14. These proceedings are discussed in greater detail in Sheila Jasanoff, "EPA's Regulation of Daminozide: Unscrambling the Messages of Risk," *Science, Technology and Human Values* 12 (1987), pp. 116–124.
15. *Ralph Nader v. EPA*, 859 F.2d 747 (9th Cir. 1988).
16. For further development of this point, see Sheila Jasanoff, "Bridging the Two Cultures of Risk Analysis," *Risk Analysis* 13 (1993), pp. 123–129.
17. National Research Council, *Science and Judgment in Risk Assessment* (Washington, DC: National Academy Press, 1994), pp. 245–263; and *Improving Risk Communication* (Washington, DC: National Academy Press,1989), pp. 19–23, 72–95.
18. These observations are based on personal conversations that I had with members of the Reinvention Committee and with Don Barnes, SAB's executive director, while serving as a consultant to the committee in 1994.
19. Nicholas A. Ashford, "Advisory Committees in OSHA and EPA: Their Use in Regulatory Decisionmaking," *Science, Technology, & Human Values* 9 (1984), pp. 72–82.
20. James C. Miller III, "Regulation and Experts: A Modest Proposal," *Regulation* 36 (November/December 1977).
21. See, generally, Sheila Jasanoff, *The Fifth Branch*, pp. 236–241.
22. See, in particular, *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519 (1978); *Baltimore Gas and Electric Co. v. Natural Resources Defense Council*, 462 U.S. 87 (1983); *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).
23. This is arguably what happened in *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987). In this case, FDA consulted with a scientific advisory panel to 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.is point, see S. Jasanoff, "Bridging the Two Cultures of Risk," *Risk Analysis* 13 (1993), pp. 123–129.