safety, and FDA was not under pressure to act within a specified time frame. The expert-committee decisions were cumulatively weighty, but individually of limited economic and political significance; technically, moreover, they were merely recommendations to FDA. Under the circumstances, the advisory panels could carry out their tasks deliberatively, incrementally, and almost invisibly. Such a posture would be virtually impossible to maintain if independent expert committees were transformed into the primary locus for decisions involving a mix of science and policy, especially in the current era of distrust for government and heightened public awareness of risk.

The PBOI marks the least radical departure from existing regulatory practice as well as the one whose utility is most questionable. In replacing trial-type administrative hearings, the PBOI may well shorten the time to reach final decisions, although the scanty history of this procedure does not allow a definitive evaluation of this point. The inquiry on aspartame, however, raises troublesome questions that must be considered if attempts are to be made to adopt the model on a wider scale. In particular, the extent of the agency's discretion to overrule the board on its technical findings should be clarified. If agencies retain complete discretion in this regard, then consultation with the board could easily become a counterproductive exercise, creating yet another focal point for contention and adding to the complexities of an already overloaded administrative process.

The most significant conclusion to be drawn from all three examples considered above is that the democratic and technocratic forms of decisionmaking maintain a creative dialectic in the U.S. regulatory process. Both EPA and FDA, it appears, are willing to tolerate departures from the "democratic" science policy paradigm in favor of more expert-centered processes, though usually in connection with narrowly defined regulatory objectives. In seeking to avoid scientific controversy, agencies can clearly resort to a wide variety of institutional and procedural alternatives, spanning the continuum from full democratic participation to specialized expert deliberation. They range from informal rulemaking, with or without scientific advice, to formal contracts with the National Academy. The challenge for regulatory reform is to determine where in this continuum science policymaking should be situated under particular scientific, legal, administrative, and political circumstances. To address this question in the light of cases considered throughout this book is a task for the concluding chapter.

11

The Political Function of Good Science

Regulatory practices at EPA and FDA would seem to indicate that the technocratic vision of public policy has scored important gains over the competing democratic paradigm. Scientific advice has become an integral part of decisionmaking at both agencies. Both are served by, and are accountable to, an impressively diverse array of ad hoc and standing expert committees. There is growing awareness in both agencies that timely consultation with outside experts can prevent controversy or, at the very least, protect effectively against challenge. Both recognize, too, that their own reputation for scientific excellence hinges on their ability to maintain productive collegial relations with the external scientific community.

Yet the picture that emerges from a close scrutiny of the advisory process does not look wholly reassuring from either a technocratic or a democratic standpoint. The contingent and socially constructed character of regulatory science challenges conventional technocratic assumptions about the nature of scientific knowledge and the role of experts. Advisory committees, we know from experience, rarely restrict their deliberations to purely technical issues. In fact, the experts themselves seem at times painfully aware that what they are doing is not "science" in any ordinary sense, but a hybrid activity that combines elements of scientific evidence and reasoning with large doses of social and political judgment. But if science is missing or obscured in the advisory process, scientists in the aggregate wield influence, and they do so, moreover, through proceedings that lack many of the safeguards of classic administrative decisionmaking. Participation by lay interests is limited and often one-sided, cross-examination is almost unknown, and committee recommendations, however much weight they carry, are seldom accompanied by detailed explanations or consideration of alternatives.

In the light of these findings, our earlier questions about the legitimacy of science-based decisions demand careful reconsideration. Must we accept David Collingridge and Colin Reeve's pessimistic conclusions about the power of science to rationalize policy, and does that view, in turn, lead to the cynical corollary that scientific advice is merely a thin disguise for the transfer of policy authority to experts? How can the notion of "improving" the scientific basis for regulation, a holdover from a discredited positivistic model of scientific knowledge, be reconciled with an analysis that emphasizes the negotiated and contingent dimensions of regulatory science? And how important, finally, are traditional forms of public participation in the advisory process? Is it desirable for expert committees to involve multiple political viewpoints in their deliberations? More generally, do procedures for advice-giving bear in any meaningful way on the ultimate social acceptability of policies based on esoteric and incomplete knowledge?

We begin this chapter by reexamining the connections between scientific advice and policy formulation and the strategies by which expert advisers achieve technical and political legitimacy. A point that emerges forcefully from the documented cases is that scientific advisory proceedings—no less than administrative proceedings of a nontechnical kind—are most effective in building consensus and guiding policy when they foster negotiation and compromise. The definition of "good science" by advisory committees emerges in this light as an important adjunct to the more openly political negotiations that underlie the development of regulatory policy. In the concluding sections of the chapter, we explore the implications of this analysis for future relations among agencies, their scientific advisers, and the public.

From Advice to Policy

Although pleas for maintaining a strict separation between science and politics continue to run like a leitmotif through the policy literature, the artificiality of this position can no longer be doubted.[1] Studies of scientific advising leave in tatters the notion that it is possible, in practice, to restrict the advisory process to technical issues or that the subjective values of scientists are irrelevant to decisionmaking. The negotiated and constructed model of scientific knowledge, which closely captures the realities of regulatory science,

rules out the possibility of drawing sharp boundaries between facts and values or claims and context. While policymakers may not openly subscribe to this view of science, it is worth noting that they, too, have retreated from a rigid support for separatism. A new flexibility is apparent in EPA's approach to scientific advice, with the result that advisory committees now have significantly more say in that agency's science policy determinations.

Evidence from regulatory case histories suggests, further, that proceedings founded on the separatist principle frequently generate more conflict than those which seek, however imperfectly, to integrate scientific and political decisionmaking. The example of the ozone rulemaking remains especially striking in this regard. In the first NAAQS revision, EPA staff members jealously guarded their prerogative to make science policy determinations such as the definition of "adverse health effect." This attitude, however, led to an unmanageably adversarial relationship between the agency and its expert advisers. The SAB committee became convinced that EPA was encroaching on matters that should have been left to scientists, and this view was eagerly exploited by the agency's industrial critics. By the time the ozone NAAQS came up for a second revision, EPA had adopted a much more conciliatory posture. CASAC members now were free to comment on any issues they deemed important at the borderline of science and policy, and their final dispositions with respect to these matters were markedly more supportive of EPA.

By contrast, confrontationally structured peer review in the Alar case was much less effective in resolving the scientific debate. The SAP initially imposed its own evidentiary standards on EPA, but at the cost of becoming too closely identified with industry's interests. The perception that EPA and its technical advisers had been captured by industry fueled NRDC's successful efforts to project an independent account of risk to the public. Alar eventually was withdrawn from the market, but public confidence in EPA suffered, and many scientists were left with the impression that the media and the environmental activist community had illegitimately seized control over the definition of good science.

FDA's proceedings on sulfites and aspartame offer similar contrasts. The ad hoc panel on sulfiting agents was formally charged with reviewing new medical information on sulfites and reevaluating the GRAS status of these compounds. The scientific issues, however, imperceptibly shaded into policy, as the panel recommended that

warning labels be used to protect specially sensitive individuals. Interestingly, this breaching of the boundary between science and policy proved to be relatively uncontroversial. The inclusive nature of the hearing, the blurring of scientific and political authority, and the panel's own flexibility defused tensions that might have persisted in a more confrontational setting. The aspartame PBOI, too, intertwined risk assessment with risk management, but here the choice of process threw into sharp relief the panel's crossover from science into policy, producing an unstable decisionmaking environment. Critics rightly complained that a science court was an inappropriate forum for deciding questions of regulatory policy. Ironically, as well, the PBOI's quasi-judicial status attracted notice and sparked questions about its disciplinary breadth and technical competence, thus detracting from its scientific authority. These charges so weakened the Board that FDA was ultimately at liberty to disregard its findings as a basis for policy.

Acceptable Risk

Decisions whether or not to accept a certain level of risk are generally regarded as involving both personal and social values,[2] and hence as inappropriate for delegation to experts. In practice, however, advisory committees are often drawn into determining acceptable risk, particularly when making threshold decisions about the adequacy of evidence. This determination almost invariably entails a balancing of science against safety. Is the risk severe enough to warrant immediate regulatory action, or should one wait for more and better data? Though the answer may be couched in technical terms, as a verdict about the adequacy of the evidence, it necessarily incorporates a sociopolitically colored judgment about the acceptability of risk.

The Alar case clearly conformed to this pattern. SAP's function was ostensibly to review the technical validity of OPP's determination that daminozide and UDMH, daminozide's breakdown product, presented a significant risk of human cancer. But in recommending that OPP should wait for additional studies, the panel delivered a collective judgment that the risks of another four years of exposure to these compounds were not serious enough to justify an immediate ban. In effect, then, the committee made a risk-benefit determination of the kind that FIFRA on its face delegates to the EPA administrator. EPA's acquiescence in SAP's judgment testified to the potency of such an expert consensus. Though the advisory committee strayed beyond its expertise, the weight of its scientific authority kept policymakers from disregarding its evaluation of Alar's risk. NRDC, by contrast, launched a successful collateral attack on the committee's findings by stressing not only the magnitude of the hazard but its possibly disproportionate impact on children. This strategy worked brilliantly precisely because it *re*politicized a supposedly technical issue by highlighting—or, to use a theatrical metaphor, foregrounding—its subjective, emotive, and political constituents.

FDA's advisory committees likewise have great power to decide whether a given body of evidence establishes safety or justifies regulatory intervention. In making such determinations, committees necessarily weigh the risks and benefits of alternative regulatory strategies, although this analysis may never be made explicit except in closed committee meetings. Thus, when the sulfites panel decided that the reports of adverse reactions were sufficiently serious to merit regulatory concern, it implicitly balanced the risks to asthmatics and salad-bar users against the benefits to society of continued sulfite use and more definite information about causal connections. The risks in this case were adjudged more significant than the benefits. The aspartame PBOI similarly determined that approval of the sweetener was too risky given the uncertainty of the evidence. Some of FDA's drug advisory committees acted in a comparable spirit in demanding stronger evidence of safety before clearing a drug for a new use or indication.

In a somewhat less transparent way, the OSTP risk-assessment document also illustrated the power of scientific advice to influence the definition of acceptable risk levels. Many of the principles of cancer risk assessment endorsed by OSTP were previously well entrenched as principles of administrative decisionmaking. For example, every federal risk-assessment policy beginning with EPA's cancer principles accepted the proposition that animal carcinogens should, in the absence of persuasive counterevidence, be regarded as human carcinogens. Agencies, in other words, saw the risk of cancer as severe enough to justify reliance on indirect evidence from other mammalian species. However, it was OSTP's effort to gather a substantial scientific consensus around these principles that finally gave them sufficient weight to withstand political challenge. In EPA's confrontation with OIRA over the risk-assessment guidelines, the regulatory agency prevailed largely because it could fall back upon the scientific consensus built by OSTP and further ratified by the SAB.

Thus, a key set of administrative policies for determining acceptable risk assumed political authority only after extensive review by outside experts certified them as adequately "scientific."

Scientific Advice as Legitimation: Negotiation and Boundary Work

What emerges from a successful recourse to scientific advice, then, is a very special kind of construct: one that many, perhaps most, observers accept as science, although it both shapes and is shaped by policy. That such constructs sometimes break down under political pressure is hardly surprising. Their frequent durability is the greater puzzle, for they are founded neither on testable, objective truths about nature, as presupposed by the technocratic model of legitimation, nor on the kind of broadly participatory politics envisaged by liberal democratic theory. To explain this puzzle, we turn to two microprocesses familiar both from regulatory case histories and from the social studies of science: negotiation and boundary work.

Regulatory practices at EPA and FDA support the thesis that negotiation—among scientists as well as between scientists and the lay public—is one of the keys to the success of the advisory process. The importance of incremental adjustments among divergent scientific viewpoints was clearly seen in the evolution of the federal guidelines for cancer risk assessment and in the equally troubled regulatory history of formaldehyde. Both cases began with the interested parties widely separated, conceptually as well as politically, but the differences lessened over time as the parties were gradually drawn into the negotiating process. For issues on a smaller scale, even a single proceeding may suffice to create scientific closure, provided it brings together in a negotiating format the majority of parties with a stake in the policy outcome. FDA's sulfite proceedings and some CASAC reviews testify to this point.

Contrary to the presumptions of the technocratic model, negotiation among scientists alone is not sufficient to ensure the public and judicial acceptability of agency decisions based on regulatory science, even if the experts in question represent a wide range of disciplinary and institutional affiliations. The protracted controversy over formaldehyde makes a powerful case that, when the stakes are high enough, no committee of experts, however credentialed, can muster enough authority to end the dispute on scientific grounds. The

broadly representative federal panel on formaldehyde, for example, provided CPSC no tangible support in fending off an industry-initiated lawsuit, just as the use of a similar panel by FDA failed to persuade the D.C. Circuit that the agency was correct in its reinterpretation of the Delaney clause. Other efforts, such as the ambitious, scientifically pluralistic, formaldehyde consensus workshop, were equally ineffectual in establishing definitive interpretations of the evidence for use in making policy.

It could be argued that SAB's review of EPA's formaldehyde risk assessment built a robust scientific consensus without intervention from political actors. This procedure, however, was woven into a lengthy rulemaking process that included many prior attempts to define the scientific status quo. Accordingly, although EPA's credibility was not seriously challenged after publication of the revised risk assessment, it is unclear how much of the credit can be assigned to SAB's peer review. By the time the SAB looked at EPA's risk assessment, the scientific dossier on formaldehyde was much larger than in 1980, when CPSC first attempted to ban UFFI. Accumulating epidemiological evidence had persuaded most observers that formaldehyde was not an especially potent human carcinogen. At the same time, referral of the textile-worker issue to OSHA had lowered the formaldehyde industry's stakes in the outcome of EPA's rulemaking. With OSHA clearly responsible for regulating occupational exposures, any risk assessment carried out by EPA carried fewer consequences than at the time of the initial TSCA Section 4(f) controversy. Finally, industry's technical ability to control formaldehyde had improved to the point where many companies either voluntarily reduced exposure or left the market altogether. In the face of these developments, it would be unrealistic to insist that scientific peer review was the most important factor in defusing the formaldehyde debate.

While the formaldehyde case illustrates the importance of "ripeness"[3] in negotiations over regulatory science, EPA's relations with CASAC and SAP underscore the importance of procedural regularity. In the first ozone rulemaking, for example, EPA's evasion of its designated advisory body proved politically costly. The short-term advantage conferred by the Shy Panel was more than offset by the negative publicity generated by the use of this ad hoc and seemingly biased advisory body. Similarly, the dissolution and reconstitution of the SAP under an anti-environment administration broke the con-

tinuity of its relations with EPA and contributed to the impression that the panel was captive to business interests. In turn, OPP's own departure from established administrative practice in seeking expedited action on Alar damaged its credibility with the advisory panel.

If negotiation is the engine that drives the construction of regulatory science, boundary work is the casing that gives the result legitimacy. Boundary work by scientists grows out of a premise that seems diametrically opposed to the concept of negotiation and yet is equally essential to the closure of controversy. By drawing seemingly sharp boundaries between science and policy, scientists in effect post "keep out" signs to prevent nonscientists from challenging or reinterpreting claims labeled as "science." The creation of such boundaries seems crucial to the political acceptability of advice. When the boundary holds, both regulators and the public accept the experts' designation as controlling, and the recommendations of advisory committees, whatever their actual content, are invested with unshakable authority.

Scientific advisory proceedings, as we have seen, provide many opportunities for boundary work by agencies as well as their advisers,[4] and committees on the whole have been quite successful in designating as science any issues on which they wish to exercise influence. Curiously, however, the most politically successful examples of boundary work are those that leave some room for agencies and their advisers to negotiate the location and meaning of the boundaries. Examples include FDA's negotiations with its drug advisory committees about the application of legal as opposed to scientific standards of evidence and EPA's gradual softening of its conceptual boundaries in its relations with the SAB and CASAC. The rigid boundaries created by the SAP in the dicofol and Alar cases, by contrast, were easily overwhelmed by NRDC and the discussion of science was moved to a populist forum—television—much to the distress of those who wished to restrict the debate to more expert-dominated settings.[5]

Defining "Good Science"

The picture presented above of the advisory process is markedly at odds with the simple technocratic paradigm of "speaking truth to power," although, paradoxically, not inconsistent with it. According to this account, the committees attached to EPA and FDA do indeed help the agencies define good science—and this consensus view of

science in turn influences policy—but they perform this function in part through skilled boundary work and in part through flexible role-playing. Protected by the umbrella of expertise, advisory committee members in fact are free to serve in widely divergent professional capacities: as technical consultants, as educators, as peer reviewers, as policy advocates, as mediators, and even as judges. Though their purpose is to address only technical issues, committee meetings therefore serve as forums where scientific as well as political conflicts can be simultaneously negotiated. When the process works, few incentives remain for political adversaries to deconstruct the results or to attack them as bad science. This stabilizing impact of expert advice can be observed at four critical junctures in the evaluation of regulatory science: validation of long-term research strategies; certification of study protocols and analytical methodologies; definition of standards of adequacy for scientific evidence; and approval of inferences from studies and experiments. Admitting the scientific community into each of these areas of decisionmaking produces a stronger consensus than any achievable through the agency's in-house expertise alone.

Research Strategies

One of the least visible activities of advisory committees is to guide the development of agency research programs. Scientific advice is here furthest removed from regulatory policy. Yet it is arguably in this area that the agency-advisory relationship produces some of its most beneficial results. In EPA's case, for example, both SAB and CASAC played a constructive role in reorienting the agency's research priorities toward greater attention to basic research on long-range environmental problems. Over time, such advice has positive, though diffuse and delayed, consequences for the credibility of regulatory science. It decouples the production of knowledge from immediate political pressures, thereby bringing the goals of regulatory science (see Chapter 4) into closer alignment with those of research science. This rapprochement, in turn, helps to solidify the agency's reputation for expertise and, with it, the overall scientific credibility of regulation.

Protocols and Analytical Methods

Just as peer reviewers generally cannot detect fraud or fabrication in scientific publication, so advisory committees will fail to uncover most instances of intentional misrepresentation in regulatory science, such

as the CO studies submitted by Wilbert Aronow to EPA.[6] The expert committees attached to EPA and FDA do not normally review laboratory notebooks or other raw data, where problems in data generation can most easily be detected, and they have neither authority nor opportunity to carry out routine inspections of research facilities. Removed from the production of data, advisory committees are in no position to substitute for effective inspection and data-audit programs. At best, a committee may be able to render a secondary judgment about the adequacy of an agency's quality control efforts, as in the debate over the Toth studies in the daminozide case.

The scientific reputation of regulatory agencies, however, suffers far more frequently from charges of error, or "sloppy science," than from allegations of intended fraud. Conflicts over research design or analytical methods are especially likely to come to the fore in the advisory process, since problems of this type generally leave traces in the documentation provided to advisers. Thus, external advisory panels called attention to the absence of contemporaneous controls in the Love Canal study and to the failure to record times and levels of exposure in the Alsea basin study of 2,4,5-T.

Such after-the-fact attributions of error may protect agencies against unwise regulatory initiatives, but they have also proved to be both wasteful and divisive, and advisory committee resources are unquestionably better used to prevent such conflicts through careful prior negotiation of research design and methods. The tightening of peer-review procedures and good laboratory practice rules, as well as the delegation of research to the Health Effects Institute, reflects a growing commitment by both EPA and FDA to involving independent experts in the design of potentially controversial studies, thereby forestalling debacles of the kind described in Chapter 2. Payoffs from these efforts include the work of CASAC consultants in helping EPA refine the methodology of judgmental probability encoding and of the Cardio-Renal Committee in advising FDA with respect to clinical trials for antiarrhythmic drugs. Despite these improvements, however, regulatory peer review remains only a partial prophylactic against methodological disputes. Unless the review process successfully negotiates underlying political divergences, it is unlikely to protect a study from subsequent deconstructive challenges or, in Collins's terms, experimenters' regress. The fate of the intensively reviewed NCI study of formaldehyde workers speaks to the difficulty of building consensus around an issue of regulatory science after it has become politically contentious.

Evidentiary Standards

In its exploration of the relationship between regulatory policy and scientific fact, the *Ethyl* court suggested that claims not yet accepted as valid by the scientific community could nevertheless serve as a basis for regulation.[7] The opinion implied that agencies with a mandate to protect public health and the environment could draw upon their reserve of policy authority to certify scientific claims as suitable for use in policymaking. The court displayed a sophisticated understanding of technical uncertainty and the constructed character of knowledge, but it failed to appreciate that scientists as well as political decision-makers would have to be involved in negotiating claims at the boundary of science and policy. The opinion went astray in suggesting that "trans-scientific" questions, such as the adequacy of evidence, could be committed exclusively to the discretion of regulatory agencies.

The institutionalization of scientific advice, especially at EPA, has helped to rectify this oversight. Expert advisory committees now play a pivotal role in determining whether the evidence before the agencies is adequate for purposes of regulation. In the process, they may apply different and stricter standards to the data than are deemed necessary by the agency's in-house staff. During the Alar review, for instance, OPP determined that the Toth studies could be relied on for quantitative risk assessment, while the SAP, subscribing to the methodological criteria proposed by Uniroyal, held that evidence from this source was virtually useless ("not science").

The SAP in this case chose not to negotiate with EPA, but to impose on the agency a possibly excessive professional bias in favor of high levels of certainty. The fear that the scientific community will consistently pursue this strategy, however, does not find uniform justification in regulatory case histories. In reviewing the criteria document for carbon monoxide, for example, CASAC concluded that there was sufficient support for the existing air quality standard, even though some studies relied on by EPA were inconclusive and others were fraudulent. The committee's acceptance of the existing record, despite its inadequacies, reflected a willingness to temper scientific considerations with concerns for public health. The Federal Panel on Formaldehyde displayed a similar public health bias when confronted by insufficient data; the panel's conclusion that formaldehyde should be presumed to pose a carcinogenic risk to humans was consistent with a preference for Type II errors (that is, regulating substances later shown to be harmless).

The expected scientific bias toward rigorous proof is perhaps most frequently encountered in the work of FDA's advisory committees, but unlike EPA in the Alar proceeding, FDA has not always felt constrained to abide by its advisers' evaluations. The standards by which the aspartame PBOI evaluated the toxicological data, for instance, were later dismissed as inappropriate by FDA. Similarly, in the propranolol and Triazure reviews, the agency disagreed with its advisers as to whether there was substantial evidence of efficacy to satisfy statutory requirements. In testimony to the Fountain committee, FDA officials, as we saw, resorted to boundary work to explain these divergences. Their claim was that the task of fitting the evidence to statutory standards belonged finally with the agency and should be carried out in accordance with legal/administrative rather than scientific/technical standards. The agency's successful defense of this position can be attributed largely to the fact that FDA's evidentiary standards led in these cases to more permissive policy results—results less likely to be challenged by industry—than were recommended by the agency's scientific advisers.

Validating Inferences

The interpretation of evidence is an increasingly important focal point for scientific advice, as regulatory agencies turn to their expert committees to certify that their conclusions are reasonably derived from the data. Questions concerning the agency's reading of scientific data are heard more frequently in EPA's advisory proceedings than in FDA's, corresponding to the fact that FDA rarely confronts advisory committees with its own independent interpretations of regulatory science. Even EPA's advisory committees, however, very seldom charge the agency with outright error in its scientific inferences, a tribute no doubt to the developing sense of cooperation between experts and agency staff. More commonly, the advisory function is geared to making sure that the agency has examined the relevant data, asked the appropriate critical questions, and couched its technical arguments in a clear and consistent manner. CASAC's supervision of the ozone criteria document and SAB's review of the guidelines for cancer risk assessment and the formaldehyde risk assessment perfectly illustrate this dynamic. In each of these cases, the advisory committee alerted the agency to problems of presentation and argument, suggesting ways in which confusions and inconsistencies might be cleared up.

As long as such review remains nonconfrontational, it certifies that the agency's scientific approach is balanced and rational and that its conclusions are sufficiently supported by the evidence. Conscientious scientific review, in other words, serves many of the same functions as judicial review. Indeed, the questions posed to advisory committees by agencies closely parallel those that litigants have traditionally posed to the courts. Is the analysis balanced? Does it take account of the relevant data? Do the conclusions follow rationally from the evidence? Is the analysis presented clearly, coherently, and in a manner that is understandable to nonspecialists? To answer these questions competently, advisory committees are required to take a "hard look" at agency decisions. If they remain unsatisfied, they may even "remand" the case to the agency for additional procedures leading to a better record (for example, SAB's recommendation that EPA consult a pharmacokinetics review panel for formaldehyde). Approval by an advisory committee, finally, is equivalent to a judicial determination that the agency action is in compliance with applicable standards of substantive rationality. We will return below to the procedural implications of this convergence between judicial and scientific review.

Normative Implications

The ultimate goal of policy analysis is to bridge from the empirical and analytic to the prescriptive. Yet this essential linkage is all too seldom attempted in works that seek to understand the nature of scientific claims and their sources of authority. Much of this book has been devoted to analyzing the processes by which advisory committees certify the validity of claims arising from regulatory science. We have established the centrality of such phenomena as negotiation, construction and deconstruction, and boundary work. It remains now to apply this conceptual framework to concrete proposals for restructuring the relations of regulatory agencies, the scientific community, and other social and political actors. What general prescriptions should agencies follow in securing expert involvement in regulatory decisionmaking? Conversely, are there procedural or institutional arrangements that should be avoided in establishing an external advisory system?

Mandatory versus Discretionary Advice

Whether scientific advice should be mandatory or discretionary has long been seen as a central question in debates about science and regulatory policy. The thrust of the preceding analysis suggests, however, that this may be a misdirected concern. The primary rationale for the advisory process is, as I have argued, to engage the scientific community in negotiating a consensus over regulatory science. The science policy paradigm of the 1970s failed largely because it did not adequately emphasize the need for such involvement by independent experts. But as long as science is institutionally well represented in the regulatory process, it should matter relatively little whether advice is sought pursuant to legal mandates contained in statutes such as FIFRA and the Clean Air Act or in accordance with established agency policy, as at FDA. Provided their interactions are regular and predictable, agencies and the expert community can be expected to develop enough confidence in each other's motives and competence to negotiate productively on scientific as well as policy differences.

There are obvious advantages to be gained from preserving some maneuvering room in the way agencies structure their relations with outside experts. As EPA's interactions with the SAB and CASAC demonstrate, it is useful for agencies to tailor their consultative processes incrementally to fit the demands of particular regulatory programs. CASAC's two-step involvement in reviewing the NAAQS criteria document and staff paper represented the endpoint of a learning process to which both the agency and the committee contributed and which neither could have foreseen at the beginning of their relationship.

Discretionary advisory systems, however, have one drawback that should not be overlooked. If agencies are free to determine when to seek advice, the decision to consult or not consult can be used as a powerful tactical weapon to delay decisions and justify inaction. Delegating a sensitive issue to an advisory committee remains one of the most politically acceptable options for regulatory agencies, even when the underlying motive is to transfer a fundamentally political problem to the seemingly objective arena of science. FDA has frequently been criticized for using its committees in this manner, and the cases of Zomax, sulfites, and color additives lend support to the charge. In the long run, however, attempts to bypass established review processes (nitrites at FDA, ozone at EPA) appear to be more

detrimental to an agency's credibility than delays occasioned by unnecessary consultation.

Committee Membership: The Issue of Balance

Given the importance of negotiation and consensus-building in the advisory process, it is clear that the ideal adviser needs to be more than a mere technical expert. This indeed squares with the perceptions of regulatory insiders, both scientists and administrators, who warn against undue narrowness in advisers. The most valued expert is one who not only transcends disciplinary boundaries and synthesizes knowledge from several fields but also understands the limits of regulatory science and the policy issues confronting the agency. Without this kind of breadth, scientists are likely to feel out of place in multidisciplinary committees and may not recognize the importance of negotiating standards of quality and certainty in regulatory science.

EPA's practices in appointing scientists to the SAB illustrate the affirmative actions that agencies can take to ensure that advisory committee members display appropriate breadth and balance. SAB members are often tested through a variety of focused appointments, such as consultancies on specific issues and membership on ad hoc subcommittees, to see whether they can function usefully in the larger theater of the full advisory board. This kind of informal testing and training is imperative to the efficacy of an advisory program and could be impeded by overly stringent requirements that advisers be drawn from particular institutions or from lists recommended by organizations such as NAS.

Agency advisers, as we have seen, must be capable of doing convincing boundary work while they are engaged in making science policy. Such a balanced performance calls for experts who not only display an informed sensitivity to the agency's mission but also enjoy unquestioned standing among their peers. Individuals who combine these traits are highly prized and may, in consequence, wield disproportionate influence. Norton Nelson's long tenure as chair of the SAB, first under William Ruckelshaus and then under Ruckelshaus's successor, Lee Thomas, can be cited as an example. Nelson's guidance undoubtedly helped to restore EPA's credibility after the trauma of the Gorsuch years and to rebuild a sense of solidarity between EPA and the scientific community. On the downside, however, such close and

long-standing relations between a regulatory agency and an individual or small group of advisers may prevent the agency from receiving fresh and disinterested advice, particularly in areas of rapidly changing knowledge.[8]

Disciplinary breadth is indispensable not only for individual scientists but for committees, especially those serving EPA, and is in any event mandated to some degree by the Federal Advisory Committee Act and statutes governing specific regulatory programs. The relatively small size of advisory committees, however, is a serious stumbling block. The SAP has been criticized throughout its existence for failing to include all relevant disciplines, and the aspartame PBOI's standing was undercut by its lack of a trained toxicologist. More specific guidance from Congress about the composition of committees is unlikely to help overcome this problem. Advances in science and in the application of scientific knowledge to risk assessment make it probable that the needs of agencies will change over time, rendering detailed legislative prescriptions obsolete. For example, toxicologists and biostatisticians are now considered essential for most EPA committees, although these areas of expertise were scarcely represented in the agency's advisory network before the 1980s.

Securing a balance of political views on advisory committees presents a still more difficult problem. If one accepts the proposition that scientific knowledge is socially constructed, and that advisory committees offer a needed forum for negotiating such constructs, then it makes good conceptual sense to require that committees should include representatives of all relevant political (as well as scientific) viewpoints. Yet the idea of overt interest group representation on expert advisory committees has few adherents, even among those who concede in private that knowledgeable administrators can stack committees in favor of particular interests.[9] This reluctance finds compelling justification in the sociology of regulatory science as elaborated throughout this book. As we have seen, the authority of advisory committees in the U.S. policy system derives in part from accomplished boundary work; it is crucial for claims certified by agency advisers to be persuasively labeled "science." An openly political committee would not necessarily be able to engage in the boundary work required to bring about this result.

In sum, it appears that agencies must retain some discretion over the issue of political balance, though industry's discontent with the SAP appointment process and reports of political pressure on FDA committee appointments provide reasons to question whether uncontrolled agency discretion is desirable. Modest administrative changes might bring about the requisite level of control. For example, the removal of FDA committee appointments to higher echelons of DHHS is believed by some to have increased the opportunities for political manipulation. Here, corrective action by Congress might be helpful, though the issue requires fuller investigation than it has received in this book. In other cases, delegation of power to make nominations, if not actual appointments, to scientific bodies such as NAS or NSF might help to assure the scientific impartiality of nominees. Relying exclusively on such mechanisms, however, could perpetuate an "old boys' network" of advisers, an undesirable situation in a system where experts exercise considerable influence over policy. No matter how the power to make appointments is ultimately allocated, the problem of bias must also be countered to some extent through administrative rules dealing with such issues as vacancies, staggered terms, and conflicts of interest.

Conflicts of Interest

Many federal laws and regulations dealing with conflicts of interest explicitly address the problem of experts or advisers who have a financial stake in the matter with respect to which they are giving advice. These provisions may be more or less effective depending on how scrupulously they are enforced, but even when vigorously implemented, they conceive of conflicts of interest in overly narrow terms. A social constructivist perspective on the advisory process suggests that there are more subtle patterns of influence that should also legitimately concern policymakers.

One troubling phenomenon (noted in Chapter 7) is the appearance of former advisory committee members as consultants for one or another party to a regulatory controversy. Even when such advocacy remains strictly within the limits of the law, it may distort the review of evidence. It is only to be expected that an advisory panel will listen with special respect to one of its own former members. Recent experiences with scientific fraud and misconduct indicate that such collegiality may lead, in turn, to a suspension of critical judgment in the evaluation of scientific claims. Accordingly, it might be reasonable to place some further restrictions on agency advisers, for example, a requirement not to appear as advocates on *any* matter before a panel

on which they have recently served. Recurrent appearances by the same witnesses, especially former agency officials, could also distort the dynamics of scientific advice, in the same way that repeat witnessing poses problems for courts, but this is a structural problem for which there are no easy solutions.

Targets of Review

In consulting scientific advisory bodies, agencies have to decide as a threshold matter what should be reviewed and what questions the experts should answer. Advisory processes at EPA and FDA reveal two fundamentally different approaches to these issues. FDA's advisory committees are generally asked to review the primary scientific data and to arrive at a preliminary assessment of risk. At EPA, however, the agency staff prepares the initial literature review and risk evaluation and then seeks comments from the advisory committee.

EPA's approach virtually invites divergences between the construction of data by the agency staff and that of the expert committee, which may operate, as we have seen, with very different standards of quality control and a different philosophy of risk assessment. This is precisely what happened in the cases of Alar, 2,4,5-T, nitrites, and ozone. In each instance, the agency's credibility suffered, for the elite advisory committee's judgments carried more weight than did those of the relatively less credentialed agency staff. FDA's preferred approach avoids this particular problem, for the advisers, rather than the agency, prepare the initial construction of risk. The danger for FDA is that the agency may be compelled to follow its advisers' opinion even on mixed science policy questions, though FDA officials can take comfort from the fact that they have been able to overrule their advisory committees on numerous occasions.

The Advisory Process: Procedural Options

I have argued throughout this book that submitting science policy disputes to adversarial processes promotes an unproductive deconstruction of science and fosters the appearance of capture. It follows from this analysis that the format least likely to bring about a durable consensus on contested technical issues is one that leads to confrontation between alternative constructions of uncertain scientific data. These points were highlighted in the Alar review, where EPA and Uniroyal confronted each other as disputants, while the SAP was cast

in the role of an adjudicating body, a miniature science court. Deconstruction proved relentlessly one-sided in this instance, for the proceedings left no practical opportunity for EPA to contest the case presented by Uniroyal experts. Accordingly, issues that might have benefited from deeper scrutiny, such as the scientific validity of Uniroyal's bioassay criteria or the biases of company experts, were left unexamined. At the same time, SAP's judgment as to which set of claims constituted good science appeared prejudiced to the watching environmental groups and failed to win their allegiance.

Closely related to the choice of procedure is the question of who should participate in advisory committee proceedings. At a formal level, agencies have little or no discretion to insulate the process of review from public scrutiny. The requirements of federal open government laws, as well as each agency's own organic statutes, apply to almost every meeting at which agencies seek advice from a specially charged expert body. But there is also little doubt that advisory committee meetings command less attention from the environmental and consumer communities as a rule than formal administrative hearings. As revealed in dozens of meeting transcripts and interviews with agency staff, public interest groups rarely attend routine advisory committee meetings. Industry, in contrast, is generally well represented, a state of affairs that no doubt reflects the resource differences between the private sector and the public interest community.[10] Accordingly, significant policy decisions, particularly decisions not to act, may be reached after advisory deliberations that effectively engaged only one set of interests. This, in turn, may lead to skepticism about the scientific claims certified by an advisory committee.

Even when legal requirements of open meetings are met, of course, not all aspects of an agency's dealings with the scientific community are automatically open to the public. When OSTP sent its risk-assessment principles out for review, or when the panel on color additives reviewed CTFA's risk assessments, the public was not notified. Similarly, the sulfite panel first met in closed session to prepare its preliminary assessment of the literature; only when the draft document was ready to be circulated did the committee make its position known to the public. Last, but not least, experienced panelists acknowledge that there are often opportunities for private, after-hours discussions among experts even in the interstices of official public meetings. Such closed sessions not only are unavoidable but are essential to any process of scientific consensus-building that has a substantial political component.

Within these constraints, however, agencies can take steps to enhance participation. First and foremost, deliberate attempts to bypass public participation, as in the notorious case of the formaldehyde "science court," are obviously to be avoided. Second, the lay public's interests can be served in many instances through good-faith efforts to consult a broad cross-section of the expert community, so that agency conclusions are not tainted by marginal science or extremist politics. For instance, participation by scientists from federal agencies and research institutions may effectively substitute for direct involvement of citizens. Agencies can also expand the roster of potential advisers by seeking nominations through varied channels, from announcements in the *Federal Register* to solicitation of scientific professional societies. Finally, even limited opportunities for the public to participate may be adequate when science advice is not closely tied to specific regulatory decisions, as for example in the development of research policy guidelines.

A third procedural issue for agencies to consider is how often to consult a committee in the course of a single rulemaking. Repeated consultation obviously reduces the possibility that nonnegotiable differences will develop between the agency and its advisers. Most committees, however, are overworked and operate under tight time and budget constraints that make multiple reviews of the same regulatory proposal unthinkable. Exceptions can routinely be made only for such complex and economically consequential proceedings as the regular revision of NAAQS for criteria pollutants. A more modest approach that holds promise for many regulatory programs is to involve the advisory committee in looking at the evidence before the agency undertakes a comprehensive risk analysis. An early review of the adequacy of the data may prevent a scientifically unwise regulatory initiative from proceeding too far for comfortable reversal.[11] Finally, such low-cost procedural changes as EPA's practice of formally responding to the SAB chairman and committee members could foster a better understanding between regulators and their advisers and lead in the long run to more cooperative and fruitful interactions.

Scientific Advice and Judicial Review

The introduction of more numerous and, in some cases, more powerful procedures of scientific review raises the question whether judicial review has become redundant in areas of highly technical decision-making. The internal logic of the administrative process clearly provides strong reasons for courts to adopt a highly deferential posture with respect to a scientific record that has undergone thorough peer review. It is not very likely, after all, that a technically illiterate judiciary will detect flaws in scientific reasoning that has already been examined by a competent expert body. Where the court is satisfied that the agency has been made to look hard at the evidence, the standard for reversal would appropriately be strict, perhaps equivalent to that for a judgment notwithstanding a jury verdict. At the same time, courts must be careful not to defer excessively to expert judgments on matters of policy. If the record suggests that a difference of opinion between administrators and experts involved substantial policy considerations—as, for example, in the Alar decision—courts should not hesitate to probe beneath the surface of an advisory committee's recommendation and, if necessary, to overrule it.

Such is the power of scientific boundary work, however, that courts may have considerable difficulty discerning when a committee has strayed over the indeterminate border between science and policy. Other warning criteria may therefore have to be identified. In general, the arguments for close judicial scrutiny are likely to be strongest when one or more of the following conditions are met: the agency and its advisers disagree in their assessment of the evidence; the agency acts contrary to the recommendations of a peer-review panel; there is evidence of procedural impropriety in the review process. For the rest, when a smoothly functioning advisory process is in place, as in EPA's air pollution control program, the rationale for judicial intervention on substantive issues will be weak at best. In such cases the spectacle of courts immersing themselves in technical data may gradually become as much an artifact as aggressive judicial overruling of congressional enactments became in the aftermath of the New Deal.

Conclusion

The realities of scientific advice at EPA and FDA contradict many of the myths and preconceptions that have grown up around this relatively unstudied process. The notion that scientific advisers can or do limit themselves to addressing purely scientific issues, in particular, seems fundamentally misconceived. Other common myths—for example, that scientists are always conservative in assessing risks or that advice is merely a pretext for delaying decisions—also seem exaggerated. Rather, the advisory process seems increasingly important as a locus for negotiating scientific differences that carry political weight.

Scientific advice may not be a panacea for regulatory conflict or a fail-safe procedure for generating what technocrats would view as good science. It is, however, part of a necessary process of political accommodation among science, society, and the state, and it serves an invaluable function in a regulatory system that is otherwise singularly deficient in procedures for informal bargaining.

Since scientific knowledge is in perpetual flux and demands constant renegotiation, interactions involving advisory committees have to be structured in accordance with norms more flexible than those of formal and informal administrative rulemaking. Repeated rounds of analysis and review may be required before an agency reaches a conclusion that is acceptable at once to science and to the lay interests concerned with regulation. The cases discussed in Chapter 9 illustrate the futility of calling on science to cut short a policy controversy before the groundwork has been laid for accord among disparate social and political values. Adversarial procedures likewise have little to recommend them in this context, for they lead not to consensus but to counterproductive deconstructions of competing technical arguments.

Finally, the negotiated model of regulatory science suggests that the risks of science seizing the reins of decisionmaking from political institutions may have been overdrawn. Negotiation commits scientists, no less than other actors, to moderating their views toward a societal mean. The regulatory experiences of EPA and FDA indicate that it is almost inconceivable for a marginal scientific school to dominate the entire spectrum of decisions about the environment or public health and safety. The primary concern for regulators, then, is not how to guard against capture by science but how to harness the collective expertise of the scientific community so as to advance the public interest. In this effort, agencies and experts alike should renounce the naive vision of neutral advisory bodies "speaking truth to power," for in regulatory science, more even than in research science, there can be no perfect, objectively verifiable truth. The most one can hope for is a serviceable truth: a state of knowledge that satisfies tests of scientific acceptability and supports reasoned decisionmaking, but also assures those exposed to risk that their interests have not been sacrificed on the altar of an impossible scientific certainty. If advisory committees can help agencies and their adversaries to reach this kind of understanding, then the "fifth branch" will indeed have helped the fourth to come of age.

Notes

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