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Public Accountability of Advisory Committees

Sidney A. Shapiro*

Introduction

One common avenue for public participation in regulatory decisions is the public advisory committee. In some cases, advisory committees expose regulatory agencies to a wider range of scientific and policy viewpoints than they might otherwise obtain. In other cases, advisory committees can prejudice the decision making process by issuing biased or uneducated advice. Recognizing this potential, Congress has established procedures designed to make advisory committee deliberations more accountable to the public. These procedures, however, may be insufficient to establish accountability for advisory committees that assist agencies in the regulation of hazardous chemicals.

Advisory Committees and Public Accountability

Some important regulatory issues are resolved by Congress, but more often the questions are delegated to health and safety agencies.¹ Advisory committees have a role to play in holding agency administrators accountable for the way in which they resolve these questions. When the product of a committee's deliberations is placed in the administrative record, it is available to those who engage in political

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¹ Aronson, Gellhorn, and Robinson, *A Theory of Legislation Delegation*, 68 CORNELL L. REV. 1, 21-24, 43-45 (1982); Pierce and Shapiro, *Political and Judicial Review of Agency Action*, 59 TEX. L. REV. 1175, 1197-98 (1981).

and judicial oversight of the agency. If an administrator takes actions inconsistent with a committee's recommendations, and the administrator fails to explain adequately the departure, overseers are more likely to modify or reverse the decision. For example, if an administrator relies on scientific data which a committee found to be unreliable, those who review the administrator's decision are more likely to scrutinize the decision more closely. In this manner, the committee's input constrains the administrator's discretion.

Advisory committees, however, also have the potential to make the administrative process less accountable. There is a potential that government power will be delegated to private parties, that committees will issue biased or uneducated advice, or that administrators will inappropriately use committees to bolster preconceived policy preferences.

If an administrator merely accepts the advice of an advisory committee, without independent evaluation of the merits of the advice, the official will have delegated a regulatory decision to private parties. The Supreme Court has held that the Constitution does not permit the delegation of public policy matters to private parties because they are entirely outside the system of checks and balances that serve to constrain the exercise of discretion by government officials.²

Committee advice can be biased if a committee is only composed of persons with similar backgrounds and experiences. For example, individuals employed by industry tend over time to adopt a point of view consistent with their employer's interests. Even if the effect is so subtle that it is unnoticed by an individual, it still can influence the type of advice the person will give.³ Similarly, persons employed in the

² Carter v. Carter Coal Co., 298 U.S. 238 (1936); see generally, Jaffe, *Law Making By Private Groups*, 51 HARV. L. REV. 201 (1937).

³ T. GREENWOOD, KNOWLEDGE AND DISCRETION IN GOVERNMENT REGULATION 194 (1984).

same scientific subspecialties develop similar biases. Disciplinary bias can greatly affect the determination of such issues as carcinogenicity because persons in different fields will weigh different types of scientific evidence differently.⁴ In some cases, an agency administrator may not realize that the advice he or she is being given is different than that a more balanced committee might present.⁵

Scientific or technical advisory committees also have the potential for issuing uneducated advice by departing the confines of science, where technical expertise is critical, and wandering into the realm of policy, where technical expertise has no particular virtue. A good example is the level of certainty demanded before drawing a conclusion that a possible cause is associated with a particular effect. Scientists are generally unwilling to draw cause-effect conclusions from statistical data absent a high degree of confidence that the observed association did not occur by chance. For purposes of publishing scientific papers and establishing scientific reputations, this degree of conservatism is entirely appropriate. But an administrator may decide not to demand such a high degree of confidence when the lives of hundreds of people are at stake. Instead, the policy maker may decide to err on the side of safety. Another administrator implementing a less protective policy might require a greater degree of confidence. Whatever degree of confidence is

⁴ Ashford, *Advisory Committees in OSHA and EPA: Their Use in Regulatory Decisionmaking*, 9 SCL, TECH. & HUM. VALUES 72, 77-78 (1984). Another example of the professional bias is that of practicing health professionals, such as the largely academic, but clinically oriented physicians, who have dominated the advisory committees of FDA's Bureau of Drugs. Because these individuals tend to be activist in their pursuit of improved human health, advisory committees at FDA often express a greater willingness than the FDA's staff to permit marketing of a drug that would be efficacious, but which would also involve some risk. T. GREENWOOD, *supra* note 3, at 194.

⁵ See R. WEGMEN, *THE UTILIZATION AND MANAGEMENT OF FEDERAL ADVISORY COMMITTEES* 41-45 (1983). A similar problem is created when members of a committee have a financial interest in the outcome of the matter for which they are giving advice.

chosen, however, is question of policy, not of science.⁶

Members of scientific or technical advisory committees often do not admit, and may not even recognize, when they exceed their expertise and based recommendations on policy values. This result not only obscures the distinction between science and policy decisions, but it can also impede the agency's decision making process. Even if the agency recognizes what the committee has done, it must attempt to explain why it wishes to reject the committee's recommendation. If the committee is composed of distinguished scientists, the agency may find it politically difficult to explain itself.⁷

Finally, as long as the policy aspect of a science/policy question is not immediately apparent to the public, a decision maker can use an advisory committee to shield himself or herself from criticism for policy choices by maintaining that the decision was made in accordance with the neutral advice of an independent scientific advisory committee.⁸ This strategy can be implemented by "stacking" the committee with scientists whose past actions indicate that they will generally resolve science/policy questions in accordance with the administrator's policy preferences or by hiding from the committee data which is not favorable to the result supported by the administrators.⁹

⁶ Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 1986 DUKE L.J. 288, 293-94; McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science-Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 731-49 (1979).

⁷ T. GREENWOOD, *supra* note 3, at 230-31.

⁸ T. GREENWOOD, *supra* note 3, at 226-29; Ashford, *supra* note 4, at 51-52.

⁹ See, e.g., Green, *The Odyssey of Depro-Provera: Contraceptives, Carcinogenic Drugs, and Risk-Management*, 42 FOOD D. COS. L.J. 567, 571-78 (1987) (FDA administrators did not disclose information unfavorable to the approval of Depro-Provera to an advisory committee reviewing the drug.); Address by T. McGarity, *Risk and Trust: The Role of Regulatory Agencies in Dealing With Risk: The Courts, the Agencies, and Congress* 16 (1985) (Presentation delivered at

Federal Advisory Committee Act

In the Federal Advisory Committee Act (FACA), Congress took several steps to promote the public accountability of advisory committees. Two of the most important requirements establish qualifications for membership on an advisory committee and create a "paper trail" of documents to explain a committee's decision. When Congress or an agency creates an advisory committee, its membership must be "fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee" and appropriate precautions must be taken to ensure that committees are not influenced by "any special interest."¹⁰ This requirement addresses the problem that a committee might give biased advice because it does not have members of opposing viewpoints or because its members have a conflict of interest. In addition, FACA requires agencies to give prior notice of meetings, to hold open meetings in most cases, to keep "detailed minutes of each meeting, and to give the public access to most committee records, transcripts, minutes and other documents."¹¹ This "paper trail" should enable interested persons, including those who oversee the agency, to evaluate the adequacy of an administrator's decision in light of the information produced by an advisory committee.¹²

Fourteenth Annual Conference on the Environment — on file with author). "Hit lists" were circulated during the transition of administrations at EPA in 1981 (which suggested that certain members of a scientific advisory committee be purged); see generally Ashford, *supra* note 4, at 51. [*Governments have sometimes used advisory committees for little more than implementing a decision made before the committee was established by appointing either (1) members who will merely "rubber stamp" government decisions, or (2) influential community leaders whose support is needed for implementation of a government decision.*]

¹⁰ 5 U.S.C. Appendix § 5(b)(2)–(3) (1982).

¹¹ *Id.* at § 10.

¹² See S. Rep. No. 1098, 92nd Cong., 2d Sess. 6 (1972). (Before FACA, "[t]he lack of public scrutiny of the activities of advisory committees was found to pose the

The Requirement of Fair Balance

The requirement that the membership of a committee be "fairly balanced" has been implemented by Congress and agencies in three ways. Some committees are balanced by specifying that members represent specific affiliations such as interest groups. Other committees are balanced by requiring that members have diverse educational and professional backgrounds. Finally, other committees are subject only to the general requirement that their membership be "balanced" without any further enumeration of what constitutes an adequate balance.

Attempts to balance committees by mandating participation by interest groups has produced an unworkable advisory committee system at the Occupational Safety and Health Administration (OSHA). OSHA is authorized to appoint ad hoc advisory committees in developing specific workplace regulations. Membership must be balanced to assure representation of the views of employers, workers, and state health and safety organizations.¹³ Although OSHA appointed advisory committees for some of its initial regulations, it stopped using the committees in 1976 because committee meetings produced partisan disagreements between persons representing labor and management.¹⁴ Although Congress intended that OSHA obtain scientific and engineering advice from advisory committees, by mandating that committees be formed on the basis of affiliation rather than scientific expertise, Congress prevented OSHA from appointing to its advisory committees leading technical and scientific experts.¹⁵

danger that subjective influences not in the public interest could be exerted on the Federal decisionmakers.").

¹³ 29 U.S.C. § 656(a)(2) (1982).

¹⁴ Shapiro and McGarity, *Rethinking OSHA: Rulemaking Reforms and Legislative Changes*, 6 YALE J. REG. 1, 35 (1989). Merrill, *Federal Regulation of Cancer-Causing Chemicals*, in ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, RECOMMENDATIONS AND REPORTS 148 (1982).

¹⁵ T. GREENWOOD, *supra* note 3, at 130.

Other agencies, where membership requirements are based on training and experience, have avoided the type of polarization that has plagued OSHA.¹⁶ The Food and Drug Administration (FDA) has a large, formalized advisory committee system to obtain advice concerning both drugs and human devices.¹⁷ Members of committees, who are selected by FDA, and who are screened for conflicts of interest must have "expertise in the subject matter with which the committee is concerned and have diverse education, training, and experience so that the committee will reflect composition of sufficient scientific expertise to handle the problems that come before it..."¹⁸

The comparison of OSHA and FDA suggests that attempts to balance membership on an interest group basis may be misguided. Based on OSHA's experience, the Administrative Conference of the United States (ACUS) recommends that members of technical or peer review advisory committees should be selected "primarily for their expertise in relevant scientific fields" rather than for their institutional or group affiliation.¹⁹ ACUS believes that Congress should replace the detailed restrictions it has created for OSHA's advisory committees with a general provision authorizing use of advisory committees subject only to the FACA requirement of balanced membership.²⁰

The minimum requirement that a committee be "balanced," however, may permit exclusion of consumer or environmental representatives

¹⁶ Shapiro and McGarity, *supra* note 14, at 48-51.

¹⁷ The Center for Drugs and Biologics at FDA has eighteen permanent advisory committees, and the Center for Devices and Radiological Health has nineteen such committees. See 21 C.F.R. § 14.100 (1987). (list of FDA's standing advisory committees); see generally Brown & Richard, *Advisory Committees and the Drug Process*, 2 J. CLIN. RSCH. 15, 16-17 (1988). (description of FDA advisory committee system).

¹⁸ 21 C.F.R. at § 14.80(b)(1)(i) (1989).

¹⁹ Recommendation 82-5, 1 C.F.R. § 305.82-5 (1988).

²⁰ Recommendation 87-10, 1 C.F.R. § 305.87-10 (1988).

from scientific or technical advisory committees. In *National Anti-Hunger Coalition v. Executive Committee of the President's Private Sector Survey On Cost Control*, the recipients of federal food assistant benefits challenged the makeup of an advisory committee appointed by the President to obtain management and cost control advice.²¹ All but three of the committee's one hundred and fifty members were executives of major corporations. The court noted that FACA requires balance only as to the "functions to be performed by the advisory committee," which in this case was to give advice concerning management and cost controls, and that the plaintiffs had no expertise in that area. The court concluded that "[s]urely Congress did not intend to prohibit the President from seeking specialized advice and while one may speculate that different choices might have been made to accomplish the President's objective the simple gathering of a discrete group of experts in a particular narrow field is not in itself enough to render such an advisory committee unbalanced in the sense of FACA".²²

In a later proceeding, the court found a violation of FACA because three of the committee's conclusions recommended repeal of existing legislation concerning specific benefits granted to poor persons such as the plaintiffs.²³ The court drew a distinction between these recommendations, which were "substantive in nature because they affect[ed] established statutory rights" and the rest of the committee's recommendations, which fell into the "narrow area of cost and management control."²⁴ As to the substantive issues, the court held the committee was not balanced because it did not contain any

²¹ 557 F.Supp. 524 (D.D.C. 1983), *aff'd*. 711 F.2d 1077 (D.C. Cir. 1983), *modified in part* 566 F. Supp. 1515 (D.D.C. 1983).

²² 557 F.Supp., at 528 (D.D.C. 1983).

²³ *National Hunger Coalition v. Executive Committee of the President's Private Sector Survey on Cost Control*, 566 F. Supp. 1515 (D.D.C. 1983).

²⁴ *Id.* at 1516.

representatives of persons who would be affected if the statutes were repealed.

The result in *National Anti-Hunger Coalition* suggests that a technical or peer review advisory committee could be restricted to persons with scientific backgrounds as long as the committee was restricted to issues that required scientific training and experience to evaluate.²⁵ Persons who serve on peer review and technical advisory committees support this outcome. They believe that balance should be sought only among persons of expert or technical backgrounds.²⁶ One argument for exclusion of nonexperts is that they would be able to offer little or no assistance concerning the resolution of technical matters. Moreover, OSHA's experience indicates that the scientific orientation of advisory committees can be disrupted if persons are appointed to represent interest groups.

Arguments also exist, however, for the including of nonexperts. As indicated earlier, it is difficult to separate scientific and policy issues and, for that reason, advisory committees often consider both issues. *National Anti-Hunger Coalition* recognized that when "substantive" or policy issues are considered, a committee is not balanced if those affected by a proposed policy decision have no representation. Moreover, the presence of nonexperts is some protection against the advisory committee operating in a manner that decreases public accountability. Finally, the legislative and administrative history of FACA indicates that the requirement of "balance" was intended to

²⁵ R. WEGMAN, *supra* note 5, at 191.

²⁶ *Id.* at 196 (1983 survey of several agencies). *See also*, Brown and Richard, *supra* note 17, at 21 (survey of persons who serve on FDA new drug advisory committees). In the survey, only nine of the respondents strongly favored inclusion of consumers and industry representatives while 51% strongly disagreed that these persons would assist the process. *Id.* at 21. *But see, e.g.*, Lakshmanan, *An Empirical Argument for Nontechnical Public Members on Advisory Committees: FDA as a Model*, 1 RISK 61, 67 (1990) (discussing two further surveys of members of FDA advisory committees).

require the inclusion of interested and knowledgeable nonexperts on advisory committees.²⁷

FDA has placed consumer and industry members on advisory committees it consults concerning over-the-counter drugs, medical devices, and biologics and, while these committees have their share of problems, participants believe they have generally functioned well.²⁸ According to FDA's rules, consumer and industry members need not have technical expertise, and, because they represent specific interests, they are not subject to the conflict of interest requirements applied to voting members, but because of such conflicts, they are not allowed to vote.²⁹

The inclusion of nonexperts as nonvoting members is a reasonable compromise concerning the issue of whether consumers or environmentalists should be placed on technical and peer review advisory committees. Nonvoting members would be able to participate in committee deliberations, or at least monitor them, without being able to influence the committee's outcome, except by the persuasion of their advocacy. For that reason, an advisory committee with consumers as nonvoting members should retain its scientific orientation and not

²⁷ Ashford, *supra* note 4 at 51.

²⁸ Friedman, *Representation in Regulatory Decision Making: Scientific, Industrial, and Consumer Inputs to the F.D.A.*, 38 PUB. AD. REV. 205, 210 (1978); Field, *GMPAC: A Perspective*, MED. DEVICES & DIAG. IND. 8 (1986); *see also* Brown & Richard, *supra* note 17, at 25. (FDA use of consumers and industry representatives has been "successful").

²⁹ 21 C.F.R. at §§ 14.80(b)(1), 14.80(b)(2)(i), 14.80(e), 14.84 (requirements for nonvoting members) (1990). Most of the FDA committees consist of nine members, seven of whom are professionals in the field of the committee's subject matter; one member represents industry and one represents consumers. Scientific members are selected on the basis of nominations submitted by interested professional groups and individuals. Industry and consumer representatives are appointed on the basis of nominations from industry and consumer organizations. Friedman, *supra* note 28, at 206.

become adversarial.

Paper Trail

If the issue of whether to include nonexperts on advisory committees is resolved against including consumer or environmental representatives, the requirement of a "paper trail" takes on greater importance. In these cases, consumer or environmental representatives must depend on the FACA requirement of a paper trail to determine how a committee reached its decision and whether committee recommendations were justified. In this manner, the paper trail serves as a "backup" or substitute protection for the requirement of a "balanced" committee.

The FACA requirements concerning the paper trail, however, may not be sufficiently specific to generate the information necessary to track the committee's deliberations. FACA requires that "detailed minutes of each meeting shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee".³⁰ At the FDA, however, the minutes sometimes only briefly summarize the disposition of a matter; they fail to identify clearly either the questions that the FDA posed to the committee or the specific answers the committee formulated and the basis for those answers.³¹

An agency (or Congress if it amended FACA) could improve the paper trail if it required advisory committees to indicate what issues the committee is to resolve, what are ways in which each issue could be resolved, which resolution the committee recommends, and why that resolution was chosen. A further improvement would address how the agency responds to the committee's recommendations. The

³⁰ 5 U.S.C. Appendix at § 10 (c) (1982).

³¹ Shapiro, *supra* note 6, at 331.

Administrative Conference recommends that when an agency rejects an advisory panel's scientific judgment, it "should explain the basis for that rejection" and "[w]hen an agency selects a regulatory approach whose basis appears inconsistent with a panel's advice, it should explain the legal, social, and other reasons that dictate or justify that choice."³²

Restrictions On A Committee's Agenda

Requiring more specific minutes should make the use of advisory committees more accountable. As an additional protection, an agency could distinguish between scientific and policy issues and restrict scientific advisory committees to the resolution of scientific matters.³³ At the current time, the questions submitted to an advisory committee can range from the scientific — "Did a study have a sound methodology?" — to the policy-dominated — "Considering the scientific data, is this chemical safe?"³⁴ As discussed earlier, the submission of policy issues to a scientific advisory committee may introduce into the panel's deliberations legal or policy issues that lie beyond its competence.

There are some disadvantages, however, to restricting the agenda of a technical or peer review advisory committee. First, it is sometimes difficult to separate the policy and scientific issues. The same issue can have both a scientific and policy aspect and the agency might want the committee to address the scientific side of the matter.³⁵ For example,

³² Recommendation 82-5, *supra* note 19.

³³ Cf. Brannigan, *The First FDA Public Board of Inquiry: The Aspartame Case* in LAW AND SCIENCE IN COLLABORATION 201 (M. Carrow & J. Nyhart eds. 1983) (FDA should submit only "scientific" questions to FDA's Public Board of Inquiry, special type of scientific advisory committee.); *see also* Note, *The FDA's Public Board of Inquiry and the Aspartame Decision*, 58 IND. L.J. 627, 639 (1983), to the same effect.

³⁴ Merrill, *supra* note 14, at 130.

³⁵ *See* McGarity, *supra* note 6, at 747-48. ("Scientists may decide a policy

an agency typically asks a committee whether a cause-effect conclusion can be made from the available statistical data. As explained earlier, the agency should not be bound by the committee's advice, because an administrator might accept a lower degree of confidence when lives are at stake. Nevertheless, it would assist the administrator in making his or her decision to know whether the scientists, applying a possibly higher degree of confidence, found a cause-effect relationship. Second, attempts to restrict the committee's agenda might invite charges that the agency has tampered with the committee's independence.³⁶ Third, although scientists do not necessarily have expertise in policy matters, individual scientists — based on their experiences with other regulatory matters — might have significant insights to offer. Finally, policy judgments require an appreciation of the nature of scientific judgments and their relationship to regulation. Scientists can help an agency understand that relationship.³⁷

In light of the previous disadvantages, an absolute ban on the submission of policy issues to advisory committees might not be beneficial in all cases. Moreover, even if an agency submits only scientific questions to a committee, it will not always be possible to confine the panel to the agency's statement of the issues to be decided. Committee members may regard the agency's statement as incorrect, or they may not be content to confine their advice to the "purely" scientific questions that they were appointed to answer.³⁸ Instead, a three step approach is warranted. First, agencies should generally refrain from referring policy questions to scientific advisory committees. Second, if policy issues are submitted to a committee, they should be clearly

question one way for purposes of scientific analysis, while regulators may resolve it in an entirely different fashion for purposes of implementing their statutory mandates.")

³⁶ Merrill, *supra* note 14, at 130.

³⁷ Shapiro, *supra* note 6, at 321–22; Ashford, *supra* note 4, at 51.

³⁸ Merrill, *supra* note 14, at 130.

labeled as such, and they should be distinct from any scientific questions which are submitted. Third, the agency should insist that a clear paper trail be established concerning how the scientific and policy questions were resolved. This last step could be implemented by adopting the previous recommendation that committees be required to indicate what issues the committee is to resolve, what are ways in which each issue could be resolved, which resolution the committee recommends, and why that resolution was chosen.

Conclusions

The public accountability of advisory committees depends on the resolution of three issues. First, what constitutes a proper "balance" in the membership of such committees? Nonexperts are typically excluded from the membership of scientific and technical committees; balance is produced by appointing scientists of different backgrounds and experiences. Accountability would be better served, however, by inclusion of nonexperts, at least in a nonvoting capacity. Second, what constitutes an adequate paper trail to indicate how the committee made its decision and on what basis? Current requirements mandating that committees keep minutes are too general. Committees should be required to indicate what issues the committee was to have resolved, an explanation of each potential resolution of an issue, which resolution the committee recommended, and why that resolution was chosen. Finally, should agencies refer policy issues to advisory committees composed solely of scientists? Because there are some benefits to obtaining policy from scientists, submission of policy issues to such committees is appropriate if rigorous safeguards are employed.