



Statement # 11

Hearing Procedures for the Resolution of Scientific Issues

(Adopted December 13, 1985)

The development of effective decisionmaking techniques for the evaluation of scientific studies has been one of the most elusive problems for the administrative process. The implementation of health and safety laws often requires an evaluation of the scientific reliability of laboratory animal, clinical, or epidemiological test data, a determination of risks and benefits based upon those data and other factors, and a final "regulatory conclusion" in which the relevant law is applied in light of the previous conclusions. For example, health and safety agencies commonly are required to determine whether a particular chemical is carcinogenic or otherwise harmful as a prerequisite to reaching a regulatory conclusion.

The quality and legitimacy of these agency decisions can be improved by counseling with eminent scientific experts outside of the agency. Some scientists and others have supported the idea of a "science court" or an institution to which administrative agencies could refer scientific disputes for resolution by expert scientists. In response, agencies have developed several methods of obtaining scientific input, including the use of advisory committees. Science advisory committees are the most common method used to obtain such assistance before an agency reaches a decision. In addition, the Food and Drug Administration (FDA) has created and used twice a unique procedure, the Public Board of Inquiry (PBOI), to obtain independent scientific review of particular regulatory decisions. The PBOI combines the elements of a "scientific hearing" with the more typical "adversarial hearing" approach for the evaluation of scientific evidence.

The PBOI is one of three alternative informal methods of proceeding that FDA offers applicants in lieu of the formal adjudication by an administrative law judge (ALJ) that would otherwise be held to review certain decisions concerning the approval of food additives and new drugs. The other two alternatives are a hearing before an advisory committee or an informal hearing before the Commissioner of FDA. The PBOI consists of a panel of three scientists appointed by the Commissioner. Two of the three scientists are selected from recommendations of the parties. The Board obtains scientific "testimony" within an informal quasi-adjudicative hearing framework, in which the advocacy role of lawyers is minimized in



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favor of a "scientific forum" approach —although the Board's decision is an "initial decision" and has the same legal status as an initial decision of an ALJ.

FDA's two PBOI hearings occurred in 1980 and 1983. In the first, a PBOI was convened to determine whether Aspartame, now a widely used artificial sweetener, should be approved as a food additive. In the 1983 proceeding, a PBOI was convened to determine whether Depo Provera, a drug approved in other countries as a contraceptive, should be approved for that use in the United States.

Some analysts contend that FDA's experiences confirm the validity of the "science court" idea for the evaluation of scientific evidence. They argue that techniques like the PBOI are more effective for obtaining scientific advice than traditional adversarial hearings because a PBOI provides the presiding scientists with the flexibility to operate according to procedures that are customary in scientific inquiry. Others suggest that the PBOI costs too much for the value of the opinions obtained from it. A study commissioned by the Conference, however, suggests that the costs or delays of the two PBOI proceedings were significantly enlarged by unanticipated management problems that can be remedied.

The Administrative Conference suggests that continued experimentation with alternative types of hearing procedures for the resolution of scientific issues is justified. Improvements are needed in management of such procedures to make them more efficient and more accurate. Examples include:

- (1) Appointing the chairperson at the start of the hearing process;
- (2) Providing additional administrative support for board members;
- (3) Separating, to the extent possible, the matters of scientific inquiry from any policy issues that may be addressed concerning the ultimate legal or regulatory actions that the agency ought to take;
- (4) Encouraging boards to utilize an experienced employee as a management adviser in the conduct of the process;
- (5) Providing an improved opportunity for direct communication between the board and the agency head upon submission of the board's decision;
- (6) Urging boards to adhere to procedures intended to ensure that the administrative record is complete and usable for successive stages of the administrative and legal process; and



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(7) Urging persons conducting agency scientific hearings in significant cases to identify the bases for their conclusions.

Other agencies with regulatory programs that depend on scientific determinations should consider experimental use of a process similar to the PBOI as a voluntary alternative to a hearing that would otherwise be held to resolve issues of scientific uncertainty. Examples of other agencies that may have similar needs and objectives include the Environmental Protection Agency, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the National Highway Traffic Safety Administration.

Citations

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