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NOTES

The FDA’s Public Board of Inquiry and the Aspartame Decision

The Food and Drug Administration must resolve difficult scientific and technological questions in promulgating and administering its regulations.\(^1\) During the 1960s the FDA encountered problems with its process for resolving scientific disputes.\(^2\) Hearings were perceived to be burdensome revealing a need for a more efficient process.\(^3\) The FDA has since attempted to improve its regulatory process by adopting summary procedures\(^4\) and by implementing new regulations to govern its rulemaking and hearing procedures.\(^5\) One new procedure is the public board of inquiry,\(^6\) a body of scientific experts that conducts hearings as scientific inquiries rather than as adversarial proceedings.\(^7\)

In 1980 the first public board of inquiry was convened to consider the safety of the sugar substitute aspartame.\(^8\) While the board withheld approval for aspartame,\(^9\) the FDA commissioner overturned the board’s decision and gave final approval for the sugar substitute.\(^10\) The eight-year approval process\(^11\) demonstrates the difficulty of regulatory decisionmaking and provides a context within which to examine the utility of the new board mechanism.

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3 See infra notes 16-30 and accompanying text.

4 See infra note 22.

5 21 C.F.R. § 12.32 (1983), authorizes parties to any proceeding subject to a formal hearing to agree to a hearing before one of three alternatives: a public board of inquiry, an advisory committee, or the commissioner. See R. MERRILL & P.B. HUTT, supra note 21, at 898-901.


7 Id. § 13.30.


9 Initial Decision, supra note 8, at 38,349.


The thesis of this note is that, on balance, the idea of a public board of inquiry is sound. Nevertheless, difficulties with the aspartame decision point to a need for procedural reform. This note suggests reform that would enhance the utility of the board, and concludes that the role of scientific decisionmaking bodies should be limited to clarifying areas of technical disagreement. Final resolution of matters that touch the frontier of science often is impossible, and in the face of such uncertainty, policy determinations should be for the FDA commissioner. In reaching this conclusion this note (1) examines the background of FDA promulgation of the board procedure, (2) provides a short description of FDA approval of aspartame, and (3) analyzes the utility of the board in light of the aspartame decision.

FDA HEARINGS AND THE PUBLIC BOARD OF INQUIRY

FDA regulations frequently address complex questions that exemplify a basic clash between law and science. Formal agency hearings have been criticized as being an inappropriate forum for dealing with scientific issues. As a result, the agency has developed the public board of inquiry as an alternative forum. This section describes the rationale underlying the board's procedures and delineates the operative framework of the board.

Rationale For Using Board Hearings

Compliance with the minimal statutory requirement for hearings was one reason for the FDA's promulgation of the board concept. Originally, the Federal Food, Drug, and Cosmetic Act required a formal evidentiary

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\[14\] See infra notes 20-22 and accompanying text.


\[16\] See Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 371(e) (1976). This section provides in pertinent part:

As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

hearing for every proposed regulation, regardless of controversy. The Act later was amended to require such a hearing only upon objection to a proposed regulation and a subsequent request for a hearing. Formal hearings are not presently held when proposals are considered by the agency; rather they are held to resolve disputes arising from final orders. The agency uses hearings whether formal or informal, primarily to create a record for judicial review and to give affected persons an opportunity to question the agency’s factual determinations. Utilization of a board hearing thus fulfills the statutory mandate in situations where a hearing is required, but a formal hearing is inappropriate.

A second reason for promulgating the board concept was that the FDA wanted to reduce inefficiency. During the 1960s, the FDA conducted what have been characterized as lengthy and inefficient hearings. In response to this criticism, the agency attempted to reduce inefficiency by pioneering the use of summary procedures to deny unmerited hearings, limiting cross-examination to the extent permitted by the Administrative Procedure Act, and promulgating regulations that allow parties entitled to a formal hearing to agree instead to an informal hearing, such as the public board.

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18 See Note, supra note 2, at 731.
19 One commentator saw three possible justifications for formal evidentiary hearings, none of which are effectively served: to develop information for making a reasonable decision, to create a record for judicial review, and to give affected persons an opportunity to question the agency’s factual premises. Hamilton, Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking, 60 CAL. L. REV. 1276, 1291-93 (1972).
21 Two hearings singled out were the Foods for Special Dietary Uses hearing, and the hearing to decide the content of peanuts in peanut butter. The dietary foods hearing had over 200 days of testimony comprising a 32,000 page transcript, and the peanut butter hearing had a transcript of over 7,700 pages. Hamilton, supra note 19, at 1287-88. President Carter stated in a news conference that “[i]t should not have taken 12 years and a hearing record of over 100,000 pages for the FDA to decide what percentage of peanuts there ought to be in peanut butter.” R. MERRILL & P.B. HUTT, FOOD AND DRUG LAW 896 (1980) (quoting from 15 WEEKLY COMP. PREs. Doc. 482, 484 (Mar. 25, 1979)). But see Dixon, Rulemaking and the Myth of Cross-Examination, 34 AD. L. REV. 389, 420 (1982) (hearing given a “bum rap”).
22 See Ames & McCracken, Framing Regulatory Standards to Avoid Formal Adjudication: The FDA As a Case Study, 64 CAL. L. REV. 14 (1976):
Recently the Food and Drug Administration has taken aggressive action to reduce the burden of prolonged administrative hearings by initiating the use of summary judgment, by allocating the burden of proof to drug manufacturers in drug efficacy hearings, and by using its rulemaking authority to its full extent so as to avoid questions of fact in both agency adjudication and judicial enforcement proceeding.
Id. See also McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 GEO. L.J. 729 (1979). McGarity writes that the FDA’s summary judgment approach has had a mixed review in the courts. Id. at 762-63.
23 R. MERRILL & P.B. HUTT, supra note 21, at 896-98.
24 See supra note 5.
A third reason for instituting the board was the FDA's desire to use advisory committees comprised of independent scientific experts to enhance the substance, credibility, and public acceptance of agency decisions. The FDA also saw judicial deference to agency expertise as a mandate to incorporate the judgment of the country's experts into FDA regulatory decisions.

A fourth reason for promulgating the board was that the FDA wished to avoid misuse or abuse of formal hearings. In its proposal of the board process, the FDA pointed to what it thought to be unnecessary interference by lawyers using the adversarial process, and noted that adversarial process is not suited to deciding scientific issues. The FDA designed the board to exclude lawyers, or at least to make them unnecessary. To this end, the regulations provide that the board is to investigate complex scientific and medical issues through scientific inquiry, not adversarial proceedings.

**FRAMEWORK OF THE BOARD**

**Board Formation**

An FDA commissioner may set up a board under three conditions: (1) when the commissioner decides that a board decision on any matter before the FDA would be in the public interest; (2) when a section of FDA regulations provide for convening a board; or (3) when a party who has a right to a formal hearing requests a board in its place. The commissioner then


28 Then Chief Counsel to the FDA, Peter Hutt, commented that administrative proceedings utilizing cross-examination accomplished little: "It has, of course, done one thing. It has employed hundreds of lawyers involved in these proceedings. But instead of advancing the scientific issue or the regulatory issue or whatever is involved, I would argue that it has set us back." Hutt, *Impact of Recent Court Decisions on the Future of FDA Regulations: An Impromptu Response to the Remarks of the Speakers*, 28 FOOD DRUG COSM. L.J. 707, 714 (1973). The introduction to the informal hearing proposal quoted Professor Gellhorn as commenting that "some of this country's gravest administrative deficiencies stem from lawyer-induced overreliance on courtroom methods to cope with problems for which they are unsuited." 40 Fed. Reg. 22,974 (1975). Thus, the regulation proposal suggested:

> [I]t is anticipated that there will be little, if any, need for participation by attorneys in the proceedings. The Participants will primarily be the scientists and others with technical backgrounds who wish to present data and information relevant to issues raised at the hearing.

Id.


chooses three board members from confidential lists of nominees.32 One list is submitted by the director of the FDA bureau responsible for the matter before the board,33 while another list is submitted by any person whose petition was granted and is the subject of the hearing.34 From these lists the first member of the board is chosen.35 The second member is chosen from lists submitted by other parties,36 and the third member, who becomes the chairman, is chosen by the commissioner from any source.37 Each list contains nominations of five persons who are to have relevant medical, technical, scientific, or other qualifications.38 Each nominee is to be aware of the nomination, willing to become a member,39 and free from conflict of interest, bias, or prejudice concerning the issues.40 The commissioner may request additional information about nominees or require additional nominations if he is unable to find a nominee who does not have a conflict of interest.41 The parties to the proceedings may agree to modify the selection process, increase the number of board members, or designate one of the FDA's standing committees as a board for purposes of the proceeding.42

Fact Finding in Board Hearings

Before notice of hearing is published, the responsible bureau must submit to the Docket Management Branch the following: the relevant administrative records; a list of persons whose views are to be presented orally or in writing at the hearing; all relevant documents, except work product, in the bureau director's files, whether favorable or unfavorable to the director's position; all other documents to be relied upon; and a statement signed by the director affirming compliance with procedure.43 Within the time prescribed by the notice of hearing, participants are required to submit items similar to the latter four items listed above,44 and must exercise "reasonable diligence" in identifying the relevant documents comparable to the bureau's documents.45 Failure to comply in good faith constitutes waiver of the right to a hearing.46 Supplemental materials may be presented

33 See id.
34 Id.
35 Id.
36 Id.
37 Id.
38 Id. § 13.10(a).
39 Id. § 13.10(b).
40 Id. § 13.10(a).
41 Id. § 13.10(c)(2).
42 Id. § 13.10(d).
43 Id. § 13.25(a).
44 Id. § 13.25(b).
45 Id.
46 Id. § 13.25(d).
only upon a showing that the supplemental information was not known or reasonably available, or that need for the information could not reasonably have been foreseen. 47

The board hearing is conducted as a scientific inquiry rather than as a trial. 48 Oral presentations may be made at the hearing, but other parties or participants may not interrupt. 49 Cross-examination is limited, 50 but board members may ask questions, 51 parties may comment on presentation, parties may ask the board to ask further questions, 52 and the board may allow any participant to ask questions if the chairman determines that those questions would be helpful in resolving the issues. 53 The hearing is to be informal, 54 with the rules of evidence not applicable. 55 However, while evidence may not be objected to as inadmissible its admissibility may be commented upon. 56 Finally, the board may consult with anyone, providing it does so at an announced meeting. 57

THE ASPARTAME HEARING

The aspartame approval process is a classic case history of regulatory decisionmaking which involves difficult scientific questions. Many elements associated with such a decision are present: a drug manufacturer whose experience with regulation has been long, difficult, and expensive, and whose clinical methods are clouded by suspicion; 56 a consumer group joined by a former Nader associate intervening to protect the public; 57 a scientist who has criticized the agency for years; 58 a commissioner with definite ideas about regulation; 59 and a controversial topic—a sugar substitute suspected of being unsafe. 60 This section describes the background of the aspartame decision, the nature of the product, the safety issues, and how the data were analyzed by the board and the commissioner.

47 Id. § 13.25(c).
48 Id. § 13.30(a).
49 Id. § 13.30(c).
50 See id. § 13.30(c)-(f)(1).
51 Id. § 13.30(c).
52 Id.
53 Id. § 13.30(d).
54 Id.
55 Id.
56 Id. § 13.30(f)(1).
57 See infra note 72.
58 See infra notes 71-72 and accompanying text.
59 See infra note 70 and accompanying text.
60 See e.g., infra notes 169-78 and accompanying text. See also New Commissioner Finds No Lack of Challenges—Or Satisfaction, FDA Cons., Nov. 1981, at 16; Hayes Intends Modest Reforms at FDA, 213 Sci. 984 (1981).
61 See infra notes 77-100 and accompanying text.
The Product

Saccharin manufacturers held a virtual monopoly on the United States low calorie sweetener market from the 1969 ban on cyclamate until G.D. Searle and Company received approval in 1981 for aspartame, a nutritive sweetener comprised of two amino acids. With aspartame approval for use in soft drinks, the value of Searle’s share of the artificial sweetener market could amount to a billion dollars by the mid-1980s. Although not as sweet as saccharin, aspartame’s advantages, so Searle advertises, are not having saccharin’s bitter aftertaste and having a complete and public safety record.

Approval Process

In 1973, Searle petitioned the FDA for approval of aspartame, and received approval the following year. However, Dr. John Olney, a psychiatrist at Washington University of St. Louis and longtime critic of the FDA’s monosodium glutamate policy, together with James S. Turner, author of The Chemical Feast and co-founder of the Center for Study of Responsive Law (Nader Research Group), and LABEL (Legal Action for Buyer’s Education and Labeling), a consumer organization concerned about chemicals in foods, raised questions concerning the safety of the product.

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See infra note 72.

See J. Verrett & J. Carper, Eating May Be Hazardous to Your Health 88-97 (1974) for a history of Olney’s dispute with the FDA over monosodium glutamate. For a different opinion of Olney see Labuza, The Risks and Benefits of Food Supply in Food Safety, supra note 1, at 323, 331. Labuza compiled a “Ted’s Terrible Ten” list of persons who have “led to mass confusion and distrust of our food supply.” Olney was on the list because he “misused scientific design of toxicological experiments to cause millions of mothers to worry about brain damage to their children from MSG.”

necessitating an FDA hearing. The parties waived their right to a full evidentiary hearing in exchange for a hearing before a public board of inquiry. Lists of nominees were submitted by Olney, Searle, and the Bureau of Foods. The acting commissioner selected a panel, and in the summer of 1979 the FDA announced establishment of the aspartame board. Issues before the board were:

1. ***whether the ingestion of aspartame, whether alone or together with glutamate, poses a risk of contributing to mental retardation, brain damage, or undesirable effects on neuroendocrine regulatory systems***

2. ***whether the ingestion of aspartame may induce brain neoplasms (tumors) in the rat***

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72 Final Decision, supra note 8, at 38,735; 46 Fed. Reg. 38,285. Dr. James Olney, see supra note 70 and accompanying text, had challenged the safety of aspartame arguing that it could be dangerous to persons suffering from phenylketonuria (PKU), a genetic disorder that prevents metabolism of phenylalanine, one of the amino acids found in aspartame. Later Olney charged that aspartic acid, aspartame's other amino acid component, is a possible source of brain damage, and that aspartame might cause cancer. Aspartame Approved Despite Risks, 218 Sci. 986, 986-87 (1981) [Hereinafter cited as FDA Approval].

Before these allegations could be contested at a hearing, however, an FDA audit of Searle clinical methods revealed "sloppy" research which included the research done on aspartame. These new revelations lowered company morale and badly shook investor confidence in the drug manufacturer. Wall St. J., July 21, 1975, at 4, col. 3. Dr. Alexander Schmidt, then FDA Commissioner, noted that the FDA had:

"found different discrepancies of different kinds. Some favored the product (Aspartame) and some [did not]." In some cases, the numbers in animal-test results didn't add up correctly . . . In some other cases, the agency had questions over the animal-testing plan itself, and in other circumstances . . . pathologists . . . had differing interpretations of animal data.

Id., Dec. 5, 1975, at 8, col. 3.

By 1976 Searle had $29 million of unrecoverable investment in the sweetener. Id., Apr. 26, 1976, at 30, col. 2. A stay on the aspartame regulation was issued. 40 Fed. Reg. 56,907 (1975). Searle halted production at its Augusta, Georgia aspartame plant and suspended a joint effort with General Foods Corporation to chart possible large scale marketing of aspartame. Wall St. J., Dec. 14, 1978, at 15. The FDA called for a grand jury investigation, id., Apr. 9, 1976, at 30, col. 2, and a study by an independent group of pathologists, Universities Associated for Research and Education in pathology (UAREP). Final decision, supra note 8, at 38,736; 46 Fed. Reg. 38,286-87; Food Additives, supra note 1, at 10-13, 28-31, 114-19, 432-39. The UAREP study took two years to complete, and approved the Searle studies as "authentic," but the FDA refused to grant aspartame approval. Id., May 8, 1979, at 21, col. 2. The delay was costly to Searle. Id. Speculation that Canada might approve the sweetener, though, sparked investor confidence in Searle. Searle's stock recommendation changed from a "sell-hold" to "buy" position. Id., Mar. 6, 1979, at 39, col. 1. Searle also began to get soft drink manufacturers interested because Searle scientists were encouraged about aspartame's adaptability for use in soft drinks. Id.


74 Final Decision, supra note 8, at 38,736; 46 Fed. Reg. 38,286.

75 Id. The board members were: Walle J.H. Nauta, M.D., Ph.D., Institute Professor, Department of Psychology and Brain Science, Massachusetts Institute of Technology; Peter J. Lampert, M.D., Professor and Chairman, Department of Pathology, University of California (San Diego); and Vernon R. Young, Ph.D. Professor of Nutritional Biochemistry, Department of Nutrition and Food Science, Massachusetts Institute of Technology. Dr. Nauta was the chairman. Id.

3. Based on answers to the above questions,
   (a) Should aspartame be allowed for use in foods, or instead should approval of aspartame be withdrawn?
   (b) If aspartame is allowed for use in foods, i.e., if its approval is not withdrawn what conditions of use and labeling and label statements should be required, if any?\

The board’s decision was specified in the notice to become final unless the parties filed exceptions. If exceptions were filed, the commissioner was to review the decision and make his own determinations.\

The board met on January 30, 31, and February 1, 1980. On the first issue it found that aspartame did not pose an increased risk of brain or endocrine dysfunction; however, on the second issue the board ruled that aspartame might cause cancer. The board then vacated the stay on the aspartame regulation and revoked the regulation, concluding that aspartame should not be marketed until further safety testing. All parties filed exceptions. In a July 18, 1981 decision, the commissioner overruled the portions of the board’s ruling finding aspartame unsafe, dismissed Turner’s objections concerning the scope of evidence considered by the board, and approved the regulation allowing marketing of aspartame for certain tabletop uses.

Data Analysis

The board and the commissioner only differed significantly on the evidence pertaining to carcinogenicity. The board noted that its consideration was limited by necessity to three studies dealing with aspartame’s propensity to cause tumor formation because these were the only studies on

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77 Final Decision, supra note 8, at 38,736; 46 Fed. Reg. 38,286.
79 Id.
80 Final Decision, supra note 8, at 38,737; 46 Fed. Reg. 38,286.
81 Initial Decision, supra note 8, at 38,346.
82 Id. at 38,349.
83 Id.
84 Final Decision, supra note 8, at 38,737; 46 Fed. Reg. 38,286.
86 Id. at 38,764-66; 46 Fed. Reg. 38,301-02.
87 Id. at 38,767-68; 46 Fed. Reg. 38,303. After reading the commissioner’s decision, two board members unofficially reversed their opinions, convinced by his rebuttal. FDA Approval, supra note 72.
88 Final Decision, supra note 8, at 38,752-64; 46 Fed. Reg. 38,294-301.
the question reported by Searle. Two of the studies troubled the board. The first was disturbing because of a high rate of death of young test rats and a possible dose-effect relationship that indicated aspartame might cause cancer. The second study was found "puzzling" because it used an insufficient number of experimental animals, and "bizarre" because the control group had a higher incidence of brain tumors than the board thought normal. The board thus found it difficult or even impossible to judge aspartame's possible oncogenity on the basis of the Searle data. Although the board concluded that the study results may have been misleading because the test animals were fed enough aspartame to cause amino acid imbalance, it decided that on the record before it an oncogenic effect from aspartame could not be ruled out.

The commissioner in turn, found error in the way the board evaluated the data for the two disputed studies. In the first study he found that the board had done an improper statistical analysis, and had made factual errors in noting age at death for certain rats. When these errors were corrected, the study was found not to indicate carcinogenicity. In the second study, the commissioner found that the board had set the normal rate of tumor incidence much too low, and thus dismissed concern over the study size after Searle had demonstrated that its study was comparable to the bureau's standard. The commissioner noted that added support for his decision came from a study by Ajinomoto affirming aspartame's safety. The Ajinomoto study had been released after the board had published its decision, but the commissioner justified including this study for consideration by noting that the proceeding was intended to be a scientific inquiry using all available evidence.

PROPOSALS FOR IMPROVING THE BOARD PROCEDURE

The aspartame decision illustrates that the board can contribute to the regulatory process. The board was successful in crystalizing and narrowing the issues and brought independent expert assessment into the deci-
A SPARTAME DECISION

It provided a forum for interested groups and individuals to criticize the FDA's determinations, and generated a record for judicial review. The board's procedure forced the commissioner to make public his position on regulatory matters and to explain how he arrived at his conclusions. Actual hearing time was of acceptable length, three days out of an eight-year process.

Both in areas of agreement and disagreement, the board and the commissioner evaluated the data differently. Some differences were trivial; others were major. The differences may be explained in terms of a combination of unrefined board procedures and more general difficulties faced by scientific decisionmaking bodies. The remaining sections of this note examine reasons for the differences in the decisions, and suggest proposals designed to improve the decisionmaking of the board.

**Scientific Uncertainty**

Part of the discrepancy between the decisions of the board and the commissioner may be attributed to scientific uncertainty for the following two reasons.

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102 21 C.F.R. § 13.10(a) (1981). The members of the board are not to be full or part-time employees of the FDA unless all parties agree to an exception. See supra note 75, for the names of the board members in the aspartame hearing.

103 See supra note 16 and accompanying text.

104 See Final Decision, supra note 8.

105 See id. Throughout his opinion the commissioner answered exceptions to the board's decision filed by the parties.

106 Searle filed its petition for aspartame approval in 1973 and received final approval in 1981. Id. at 38,734-35; 46 Fed. Reg. 38,285. The hearings were held on January 30, 31, and February 1, 1980. Id. 38,737; 46 Fed. Reg. 38,286. Perhaps the fact that the time required for the board hearing comprised only a small proportion of the approval process suggests that a review of the entire decisionmaking process would be productive. One commentator has noted that:

Stress on the purely technical aspects of the decision may not be well founded since the real issues tend to be those of a social nature. A more formal view of the entire process, the decision-making process, seems to be warranted so that the relative importance of the technical versus social aspects in making a decision can be properly assayed.


The proposal for a National Science Panel, see infra note 117, has recently taken more concrete shape in the National Science Act, Hearings Before the Subcomm. on Department Operations, Research, and Foreign Agriculture, 97th Cong., 1st Sess. (1981).

107 An example of a minor difference in interpreting data is the way the board and the commissioner treated a benchmark set by the board for comparison purposes on the PKU issue. The board used a 4 ounce hamburger as the benchmark for comparison of amounts of phenylalanine intake, but failed to take account of the fact that people actually eat cooked hamburgers. The commissioner made the adjustment, noting that the "change in no way affects the validity of the board's conclusions." Id. at 38,745 n.17; 46 Fed. Reg. at 38,290 n.17.
First, uncertainties generated by science and technology are approached differently by law and by science. The law must resolve questions inexpensively and quickly, against the background of complex, moral, economic, legal, and political considerations. Scientists need only note uncertainty and the need for research. Despite differences in approach, law and science must work together in order for the legal system to make order out of the problems introduced by science and technology. Science courts, science clerks, advisory committees, and special conferences are a few of the solutions that have been suggested as a way to improve decisionmaking on technical matters. When a science advisor or advisory group is established, a concern is that power is being given to an elite group, unaccountable for its actions. To prevent power drifting to a scientific elite, attempts are often made to separate questions of policy and fact. In the science court model, the science court makes factual determinations while the primary decisionmaker—a court, legislature, or agency—takes the factual determinations and applies societal values in making the final policy decision.

However, facts and values often cannot be easily separated. An intertwining of fact and value frequently occurs when attempts are made to

112 See Jasanoﬀ & Nelkin, supra note 12, at 1214.
113 See id.
115 The fear is of technocracy. One extreme view is quoted by Lakoff: “[W]e face the real danger of a layered society in which a scientist elite fraction floats on top and dominates our policy-making. The danger is that a new priesthood of scientists may usurp the traditional roles of democratic decision making.” Lakoff, Scientists, Technologists, and Political Power in Science, Technology and Society 355, 367 (I. Spigel-Rössing & de Solla Price eds. 1977) (quoting R. Lapp, The New Priesthood: The Scientiﬁc Elite and Uses of Power 3 (1963)). The more realistic view, though, is expressed by Lakoff:

Scientists and technologists are likely to have a signiﬁcant impact in shaping the views of those who make decisions; but except in rare cases, where the matter at issue is entirely or almost entirely a matter scientiﬁc judgment, the views of scientists are not likely to determine the outcome exclusively.

Id. at 383.
resolve issues on the border of scientific knowledge. Much may depend on scientific judgment. Differing scientific interpretations revolve around how much weight is given to different parts of available data, what assumptions are made when data are not available, which methodologies are credited, and what current scientific paradigms dictate. When scientists are unable to explain objectively their interpretations of data, their own biases may influence their determinations.

The FDA has recognized the limited role of scientific decisionmakers when uncertainties are involved. However, the FDA did not attempt to prevent consideration of value questions by the public board of inquiry in the aspartame decision. The board was required to make the legal determination of whether aspartame should be approved for marketing instead of solely deciding to what extent, if any, aspartame is harmful. Although one fear of using scientific decisionmaking bodies has been that their decisions will be given too much weight the commissioner in the aspartame

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119 See McGarity, supra note 18, at 741-42 ( "[A]lthough scientists are not immune from public policy preferences when they advise policymakers, scientific judgment has more to do with scientist's views, arising out of long years of study, on how things operate in the physical world with which they are familiar. As a result different scientists interpret the same data differently."). Cf. Gillespie, supra note 118, at 278-79 (differences in social values of advisors linked to character of science forming basis of their advice).

120 One study relating the type of occupational control over scientists to the type of knowledge they produce found that scientists "not only evaluated the same data differently, and derived contrary policy implications from the same, or similar evidence, but that also, motivated by different social and scientific commitments, they were predisposed to produce different 'facts'." Gillespie, supra note 118, at 276 (citing Johnston & Robbins, The Development of Specialities in Industrialised Science, 25 Soc. Rev. 87 (1977); Robbins & Johnston, The Role of Cognitive and Occupational Differentiation in Scientific Controversies, 6 Soc. Stud. of Sci. 349 (1976)).


In short, the significance of much of the animal testing conducted today is poorly understood, and the widely variable results obtained are subject to differing interpretations. Its usefulness in the design and execution of sound public policy under these circumstances is unfortunately limited. As a matter of practical necessity, therefore, we often regulate more out of fear of the unknown than out of respect and appreciation of the known. And until science begins to bring greater understanding to safety testing, regulation of the safety of food and drugs must be accomplished in the midst of unresolvable scientific disagreement.

122 See supra text accompanying note 77. Question 3(a) involves a value judgment.

123 Id.

124 David Bazelon, Chief Judge of the District of Columbia Court of Appeals, in criticism of the Science Court proposal, has warned that lengthy adversarial proceedings may exaggerate the importance of scientific issues and minimize the underlying value choices: "A factual decision by a Science Court, surrounded by all the mystique of both science and the law, might well have enormous, and unwarranted, political impact." Bazelon, Coping With Technology Through the Legal Process, 62 Cornell L. Rev. 817, 827 (1977); See also Talbott, supra note 106, at 860.
case had no difficulty challenging the board’s fact or policy determinations.\textsuperscript{125} The commissioner’s action lessens apprehension that a board’s determinations might co-opt the regulator’s responsibility for policy,\textsuperscript{126} and is, in fact, a positive sign that a commissioner will not be intimidated by a board’s factual determinations. The policy question, however, should never have been put to the board. The purpose of scientific decisionmaking by special bodies should be to make factual, rather than policy, determinations since this would confine the decisionmaking of these bodies to the area of their expertise.

A second reason why scientific uncertainty may have contributed to differences in the decisions of the board and the commissioner arises from the difficulty of getting appropriate and trustworthy information. Often information used to make decisions is not designed for giving answers to issues needing resolution.\textsuperscript{127} For example, in the aspartame decision the information regarding background rates of brain tumors had to be extrapolated from studies done for other purposes.\textsuperscript{128} In addition, available information often is limited. The aspartame board had only three studies on which to base its decision regarding carcinogenicity of aspartame.\textsuperscript{129} Finally, scientific knowledge is in constant flux. In the aspartame decision, evidence pointing to the possible neurotoxicity of aspartame was developed only after the original objections were filed.\textsuperscript{130} In the only other matter to date to go before a board, additional submissions of data were solicited because the board thought that the state of knowledge had changed since data were submitted two years earlier.\textsuperscript{131}

An imperfect solution to this problem is to have scientific decisionmaking bodies such as the board define the level of uncertainty in knowledge on a particular question. The regulator can then apply that definition as a factor in making the final decision on a regulatory matter.\textsuperscript{132} The board attempted to do this in the aspartame decision by mentioning that it thought the significance of the carcinogenicity studies was difficult or even impossible to evaluate\textsuperscript{133} and by stating that further studies would be necessary.\textsuperscript{134} The board also suggested factors to look for in any further studies.\textsuperscript{135} Instead of applying this determination, however, the commissioner decided the board’s concerns were unmerited.\textsuperscript{136}

\begin{itemize}
\item See supra notes 94-100 and accompanying text.
\item See Bazelon, supra note 124.
\item See Initial Decision, supra note 8, at 38,347.
\item Id. at 38,346.
\item Id. at 38,345.
\item See Kantrowitz, supra note 116, at 49-50 (science court function restricted to describing in scientific terms exact shade of grey present).
\item Initial Decision, supra note 8, at 38,348.
\item Id. at 38,349-49.
\item Id.
\item Final Decision, supra note 8, at 38,752-64; 46 Fed. Reg. 38,294-301.
\end{itemize}
Trial Type Procedures

A hotly disputed issue in the board concept is whether the use of "scientific inquiry" in place of adversarial procedures is beneficial. For example, the value of restrictions on cross-examination is disputed. In proposing the board, the FDA argued that issues before the FDA in public hearings were unsuited to adversarial procedures. However, some commentators, notably trial lawyers, dispute whether scientific issues of fact are different from other issues of fact, and contend that trial-type procedures, although not perfect, are the best way to develop facts.

When deciding what procedures are appropriate a balance must be struck between the various competing interests: fairness to the parties, the truth finding function, and the need for efficiency. The board presently uses a modified cross-examination format in which opposing parties may ask questions through the board only if the chairman decides that the questions will be useful. The procedure will vary with the peculiarities of any particular board. In order to insure more accurate fact finding, the ability of opposing parties to cross-examine witnesses should be strengthened, while the board's consideration should be limited to factual questions.

13 Compare Thompson, supra note 31, at 315 (removing adversary procedure "misguided and unlikely to succeed in the long run"), Hagan, Remarks on the Regulatory Philosophy of FDA, 28 FOOD DRUG COSM. L.J. 195, 199 (1973) (expert witness must be cross-examined in order to discover whether substantial evidence test is met), and Kennedy, The New Vogue in Rulemaking at FDA: A Foreword, 28 FOOD DRUG COSM. L.J. 172, 173 (1973) (author agrees with alarm expressed at suggestion that trial-type procedures in hearings on scientific and technical matters are useless) with Hutt, Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act, 28 FOOD DRUG COSM. L.J. 177, 187-88 (1973) (trial-type procedure inappropriate in hearings primarily scientific or technical in nature) and Hoffman, The FDA's New Forms of Public Hearing—Choosing Among the Alternatives, 32 FOOD DRUG COSM. L.J. 330, 336 (1977) (dismissing lack of cross-examination as a concern saying it is available, but just carefully not labeled as such). See also Morning Question and Answer Session, 1973 Court Cases Involving Rulemaking Implications for Federal Regulations—Morning Session, 28 FOOD DRUG COSM. L.J. 718, 727 (1973), where Hoffman in discussing the over-the-counter drug review process says the FDA cannot "dispense with cross-examination in all circumstances on all aspects of all issues that arise . . . just because not all of us lawyers can understand what all of those doctors are talking about." See also Yellin, High Technology and the Courts: Nuclear Power and the Need for Institutional Reform, 94 Harv. L. Rev. 489, 507-08 (1981) (adversarial techniques inappropriate in nuclear power decisionmaking context); McGarity, supra note 22, at 760 (courts should not insist on use of formal procedures by administrative agencies); Note, supra note 2, at 738 ("Trial methods should be avoided in rule-making proceedings."). Cf. Hutt, supra note 28, at 714 (key not cross-examination, but right to full participation).

12 See supra note 138.

14 Hutt, Philosophy of Regulation, supra note 138, at 187-88.

15 See, e.g. Hagan, supra note 138, at 199.

16 See supra notes 48-53 and accompanying text.

The opportunity to conform procedures to the needs of a particular controversy might be a great advantage in the use of the board. In the depo-provera hearing, the board held a pre-hearing conference in order to establish the methods and procedures to be used in developing evidence at the hearing, the sequence of presentations, the amount of time allotted to speakers, when and how questions by participants were to be permitted, and whether summations would be allowed. 47 Fed. Reg. 36,470 (1982).

17 See Hamilton, supra note 2, at 1168. Although generally critical of cross-examination in rulemaking proceedings, Hamilton notes that "when the issue is clearly defined and relates
A suggested format is to allow cross-examination, but to give the board authority to exclude irrelevant, immaterial, or cumulative testimony. Parties would be grouped by economic interest absent a showing that such a grouping would be prejudicial. A lead attorney chosen by each group would do any cross-examination and reasonable time limits would be imposed.¹⁴ Such a format might have been helpful for all sides in the aspartame hearing. Searle and the Bureau of Foods might have been able to cross-examine Olney's witnesses to show weakness in their statistical methods,¹⁴⁸ whereas Turner might have been able to expose weakness in the Searle studies.¹⁴⁷

The board was designed to be an informal decisionmaking body. However, adding the procedures suggested above would formalize the proceeding. Yet simply because members of the board are scientists and not lawyers does not mean that the proceeding itself should be less formal. It has been argued that scientists need informal procedures because, while they may be familiar with scientific inquiry, they will be unable to control an adversarial process. One commentator has noted that the Nuclear Regulatory Commission uses tribunals similar to the board and that, although not models of elevated scientific discourse, they use "usual adjudicatory procedures" that have proved valuable where the triers of fact are scientific experts.¹⁴⁸

The same commentators that question the efficacy of limiting cross-examination also fault the board procedure for lack of discovery devices.¹⁴⁹ The only fact generating provision in the board regulations is that parties use "good faith" and exercise reasonable diligence in turning over both favorable and unfavorable data.¹⁵₀ Reality suggests that not all parties necessarily have the same concept of good faith and that lack of good faith is difficult to prove. The FDA should adopt more liberal discovery provisions, since permitting discovery would aid in revealing potential harms.¹⁵¹

In the aspartame hearing, discovery might have allowed Olney and Turner to gather information that would support their contentions that the Searle

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¹⁴ The format proposed is basically the same as the one proposed by Hamilton for cross-examination in formal FDA hearings. Id. at 1168-69. The current board procedure is less restrictive than the limited cross-examination regulations for formal FDA hearings. Section 12.87 allows oral cross-examination only upon a showing of the need for the procedure and a showing that prejudice would result by denial of the request. 21 C.F.R. § 12.87 (1981).

¹⁴⁶ See Final Decision, supra note 8, at 38,760-61; 46 Fed. Reg. 38,298-99 (statistical analyses discussed).

¹⁴⁷ See id. at 38,764-66; 46 Fed. Reg. 38,301-02 (Turner's exceptions discussed).


¹⁴⁹ See supra note 138.


¹⁵¹ See Thompson, supra note 31, at 320. See also Koch, Discovery in Rulemaking, 1977 DUKE L.J. 295, 345 ("The investigative nature of rulemaking dictates that any improvement in the information gathering process will enhance the policy decision expressed in the rule.")
studies had been poorly conducted.\footnote{See Final Decision, supra note 8, at 38,764-66; 46 Fed. Reg. 38,301-02.} Such information would have aided them in presenting their case to the board. Discovery, however, has the potential for abuse by parties. If discovery is implemented, it will have to be carefully structured for legitimate use, and not for delay or harassment.\footnote{See Koch, supra note 152, at 345. In his conclusion Koch summarizes some of the dangers and the productive uses of discovery in rulemaking:}

Under the present procedures, if a party determines that discovery or cross-examination is necessary to support his case, that party may desire to utilize a full evidentiary hearing.\footnote{Id. One commentator warns that if a party thinks the FDA could prevail against a procedural challenge to denial of an evidentiary hearing, choosing an alternative forum may be best because the FDA has been fairly successful in denying formal hearings. Yet when the FDA is on shaky ground and fears litigation over a denial, it may be willing to accept an alternative proceeding as a compromise. Hoffman, supra note 139, at 334. When an adversary has suspect data the wisest move would be to insist on a formal proceeding because board procedures limit your ability to expose weaknesses in an adversary’s case. Id. at 335. If the party thinks he needs the expertise of independent scientists he may want to choose the advisory committee option since the board is ad hoc and may lack “regulatory perspective that comes with experience.” Id. at 337. Another consideration is that it may be easier to persuade a majority of an advisory committee than a majority of a board which has only three members. On the other hand, “membership of a public board of inquiry can be tailored precisely to fit the requirements of the case it is to hear.” Id.} With this practical consideration in...
mind, most parties are likely to demand a formal hearing, leaving the board
unused. The FDA will benefit from the board mechanism only if the board’s
procedures are attractive to parties. The procedures suggested above
should help implement the goals of the FDA in establishing the board by
making the board more attractive to potential parties.

Selection of the Board

Other possible reasons for the difference between the decisions of the
board and the commissioner are that the board members did not have the
required expertise or that they were biased. The positions the members
held at respected universities seem to negate the conclusion that the
members did not possess the expertise. However, it is possible in the pres-
et board procedure to select biased members.

The FDA’s board selection process was designed to avoid having biased
viewpoints on the board. The FDA thought that having each nominating
group submit a list of five persons would provide the agency with enough
choices to avoid selecting members who represent one party’s view. The
FDA’s view is defective in two ways. First, it ignores an advocate’s ten-
dency to build support for the position it will advance. Second, the selec-
tion process does not ensure equal representation on the board for all in-
terested groups. Either the petitioner or the bureau responsible for the
matter before the board always faces the possibility of not getting a member
on the board because only one member is selected from their combined
lists. In addition, this process does not assure that the best opposing view-
point will be represented on the board, since there may be many intervenors
whose interests are not similar.

By allowing parties to help select members, the FDA attempted to in-
crease participation in the decisionmaking process. In practice, however,
the procedure creates a selection process open to controversy, and places
potential partisans in positions that should be neutral. A possible solution
is to have an independent body such as the National Academy of Sciences

155 See supra note 75.
156 Greenberger, A Consumer Advocate’s View of the FDA’s Procedures and Practices, 32
FOOD DRUG COSM. L.J. 293, 297 (1977).
157 Lakoff, supra note 115, at 377; Greenberger, supra note 156, at 297:

Certainly, it can be expected that any individual chosen would exercise his or her independent judgment, and would not feel bound in a formal sense to “represent” the interests of the nominating party. However, nominating parties will certainly be aware of the approaches taken by individuals. It often would not be difficult to find five people whose approach, although arrived at independently, would be completely compatible with the nominating party. The whole notion of nominations from different sources obviously implies an expecta-
tion of different viewpoints.

158 Thompson, supra note 31, at 314.
159 Id.
160 Id.
select board members. The Academy has experience in selecting members for government advisory groups. Academy selection of members would lessen charges that the board members represent one viewpoint or that the FDA commissioner was biased in selection. Charges could still be made that the NAS was biased in selection, but the process would be no worse than for many other government committees.

Result Orientation

As previously noted, questions that cannot be resolved by science often must be resolved by the law. When there is such a question, and modes of analysis lead to different answers, underlying values determine how a decisionmaker decides. In the aspartame case underlying values and pressures could have influenced the decisions of the board and commissioner. The commissioner has pressures that a board does not. For instance, Searle was threatening to pursue a lawsuit against the FDA in order to generate a final decision. Societal pressures also may have influenced the commissioner more than the board because the board was partially insulated by virtue of its temporary nature. Important societal pressure involved in the aspartame decision included the previous year's decision not to allow cyclamate back on the market, and the potential ban on saccharin in the summer of 1981. Thus, aspartame disapproval could have left dieters and diabetics without a sugar substitute. These pressures may help ex-

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161 See Carpenter, Legislative Approaches: The Regulation of Chemicals in 1 CONSUMER HEALTH AND PRODUCT HAZARDS/COSMETICS AND DRUGS, PESTICIDES, FOOD ADDITIVES 1, 33, 36, 37 (S. Epstein & R. Grundy eds. 1974).
162 But cf. WESSEL, supra note 114, at 146-47 (footnote omitted):
The National Academy of Sciences and its membership are seen as strictly “establishment,” controlled and composed very largely of scientists who have “achieved” in major ways within the present “repressive” economic and social system, dependent upon government and industry for funding and other support, and certainly not reflective of the views of other less “well-fixed” opinion in the scientific world. Whether or not any of this is true is really almost irrelevant. The perception itself means that the general community does not always accord the status of true scientific “consensus” to the conclusion of a scientific panel studying a controversial issue. For all these reasons, the “scientific advisory committee” approach—valuable as it clearly is—is not enough.
163 See Turner, Principles of Food Additive Regulation in 2 CONSUMER HEALTH AND PRODUCT HAZARDS/COSMETICS AND DRUGS, PESTICIDES, FOOD ADDITIVES 289, 305-06 (S. Epstein & R. Grundy eds. 1974) (Turner notes blatant industry influence on the NAS and FASEB (the parent organization of UAREP)).
164 See supra notes 108-10 and accompanying text.
165 See supra notes 118-20 and accompanying text.
plain discrepancies in the decisions of the board and the commissioner.

Another explanation for the discrepancies in the aspartame decision is that the commissioner and the board held differing scientific philosophies which influenced the standards they used to make their decisions. The board "emphasized" that it had only three studies on which to base its decision on carcinogenicity and decided that more studies were needed,\textsuperscript{169} the commissioner admitted more studies would have been helpful, but thought he could make a decision based upon available studies.\textsuperscript{170} The board thought that the number of rats in the carcinogenicity studies was too low;\textsuperscript{171} the commissioner stated that the number was shown to meet agency standards.\textsuperscript{172}

Differences in regulatory philosophies also can influence decisions. In the cyclamate decision, a former commissioner noted that methodologies employed in animal studies "must" be considered in deciding how much weight to give a study,\textsuperscript{173} while in the aspartame decision both the commissioner and the board disallowed a request to question the manner in which studies were conducted because they thought they could rely on the UAREP authentication.\textsuperscript{174} From the language of the decision, it is unclear whether the authentication included an investigation into the conduct of the studies. Authentication seems to have centered on determining whether the studies were fraudulent and not on the manner in which they were conducted.\textsuperscript{175} While the commissioner described this dispute as a "semantic" difference on the meaning of the term "scientific validity,"\textsuperscript{176} the difference may have determined the outcome of the aspartame decision.

As the aspartame decision illustrates, many factors can determine how an issue is analyzed. For purposes of the law, however, results should be oriented toward the statutory mandate of the agency, not toward personal or political philosophies or pressures.\textsuperscript{177} For the FDA the mandate is safety.\textsuperscript{178}

\textit{Standard of Review}

The FDA's standard of safety in its regulations presents an anomaly difficult to justify in the aspartame decision. Section 409(c)(3)(A) of the Federal Food and Drug Act permits the FDA to approve a food additive only if

\textsuperscript{169} Initial Decision, \textit{supra} note 8, at 38,346, 38,348-49.
\textsuperscript{170} FDA Approval, \textit{supra} note 72, at 997.
\textsuperscript{171} Initial Decision, \textit{supra} note 8, at 38,348.
\textsuperscript{172} Final Decision, \textit{supra} note 8, at 38,762-63; 46 Fed. Reg. 38,300.
\textsuperscript{173} 45 Fed. Reg. 61,478 (1980).
\textsuperscript{174} Final Decision, \textit{supra} note 8, at 38,764-66; 46 Fed. Reg. 38,301-02; Initial Decision, \textit{supra} note 8, at 38,337.
\textsuperscript{175} Final Decision, \textit{supra} note 8, at 38,764-66; 46 Fed. Reg. 38,301-02.
\textsuperscript{176} \textit{id.} at 38,765; 46 Fed. Reg. 38,301.
\textsuperscript{177} McGarity, \textit{supra} note 18, at 782.
\textsuperscript{178} \textit{See infra} notes 179-80 and accompanying text.
the petitioner proves that the product will be safe.\textsuperscript{179} FDA regulations provide that food additive is safe if “there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.”\textsuperscript{180} This language seems to prevent the commissioner from overturning a board’s determination that it is not certain of the product’s safety, as long as that uncertainty is “reasonable” and the board members are “competent scientists.” However, in the aspartame case the board’s decision was deemed to be “initial,” thereby allowing the commissioner to review the record and make his own determinations.\textsuperscript{181} By its actions in the aspartame decision the FDA suggested that it will defer to outside advisory committees and public boards only as long as they support the bureau’s position.\textsuperscript{182} However, if an expert advisory group, such as the board, is only given lip service, then utilization of the board becomes merely a wasteful step in a repetitious process of regulation.\textsuperscript{183}

The anomaly presented above suggests that a standard of review which is consistent with the competence of the board and designed to improve its credibility should be set for a commissioner’s review of a board decision. One way to accomplish this goal, while also confining the decision-making of the board and commissioner to their respective areas of expertise,\textsuperscript{184} is to separate fact and policy issues to the extent possible,\textsuperscript{185} giving the board only the fact questions. The factual determinations of the board should then have a presumption of validity\textsuperscript{186} with a clear error standard of review. Policy determinations should be left to the commissioner, to be made within constraints mandated by the FDA organic statute.\textsuperscript{187} Section 409(c)(5)(a-c) mandates consideration of probable consumption, cumulative effect in the diet, and safety factors, and allows consideration

\textsuperscript{180} 21 C.F.R. § 170.3(i) (1983).
\textsuperscript{182} One commentator has noted a similar problem in regard to formal hearings: “Since the FDA has usually taken a position on the board policy questions before the hearing, the agency tends to view the formal hearing merely as a device for creating a record that will support previously determined administrative decisions.” Hamilton, supra note 2, at 1154.
\textsuperscript{183} Cf. FDA DRUG PROCESS, supra note 1, at 68 (“In this country, advisory committees, for the most part, are only given lip service, and the FDA makes the final decision itself.”).
\textsuperscript{184} See supra notes 121-26 and accompanying text.
\textsuperscript{185} Id.
\textsuperscript{186} Whether a decision by a scientific decisionmaking body should be binding on regulatory agencies is debatable. The National Science Panel suggested by AIHC, see supra note 117, would not make a panel’s determinations legally binding, but agencies would be expected to accept panel determinations “as the basis for planning any subsequent regulatory action.” Id. at 281. Representative Wampler’s version of the panel would make findings binding on the regulatory agency. Id. at 10 (statement of Rep. Wampler). A former administrative law judge has suggested that the hearing process could be improved by requiring that facts determined by administrative law judges be deemed final if supported by substantial evidence. Thus “full and automatic de novo review as to questions of fact,” would end. Gladstone, The Administrative Process in Administrative Law, 31 Ad. L. Rev. 237, 243 (1979).
of other factors when regulating food additives under the general safety clause.\textsuperscript{188} Thus, as suggested by one commentator regarding the regulation of carcinogens, the commissioner might consider "logistic, economic, hedonistic, esthetic, ethical, and other cultural values."\textsuperscript{189}

The aspartame case illustrates other problems in the existing board process which may have contributed to the differences in the decisions of the board and the commissioner. Moreover, a clear error standard would have yielded the same results in the aspartame decision, assuming the commissioner's evaluation of the data was correct.\textsuperscript{190} Strengthening the board's factual determinations while leaving policy issues to the commissioner's determination would add credibility to the board and eliminate repetition in the regulatory process.

\textbf{CONCLUSION}

The Food and Drug Administration must resolve difficult scientific and technological questions while administering its regulations. When FDA hearings became burdensome during the 1960s the need for a more efficient process was perceived and the public board of inquiry was implemented as one alternative to a formal hearing. Implementation of the board was meant to achieve better quality decisions on scientific matters, and to improve efficiency, through innovative procedures aimed at conducting board hearings as scientific inquiry, rather than as legal trials.

The first board was used in 1980 to consider safety questions concerning the sugar substitute aspartame. The aspartame decision reveals the difficulty of regulatory decisionmaking when scientific questions are involved. Scientific uncertainty is approached differently by science and the law, and makes decisionmaking difficult because information may be incomplete or inappropriate.

Although final resolution of scientific disagreement faced by the FDA may be impossible, the public board of inquiry is a promising procedure. The procedure has kept hearing length short, narrowed issues, provided a record for review, brought outside expertise into the decision, forced the commissioner to explain his position, and provided a forum for interested parties to express their views. Yet, in light of the aspartame decision the board procedure needs some changes. The FDA's concern with efficiency needs to be balanced with the need for adversarial procedures in order to achieve fairness for parties. Selection of board members also needs to be modified to prevent biased views from being represented on the board. The

\textsuperscript{188} Id. § 348(c)(5)(a)-(c).

\textsuperscript{189} See Gori, The Regulation of Carcinogenic Hazards, 208 Sci. 256, 260 (1980) (Gori would set definitions and rankings for consideration of these factors in regulation).

\textsuperscript{190} See supra notes 94-100 and accompanying text.
board's role should be limited to making factual determinations. The board should decide the extent of uncertainty on a matter, and board determinations should then be reviewed only on the basis of a clear error standard. These reforms would aid the public board of inquiry in making a positive contribution to the regulatory process.

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