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Consumer Representation in Standards Development: Literature Review and Issue Identification

U.S. DEPARTMENT OF COMMERCE
National Bureau of Standards
National Engineering Laboratory
Office of Engineering Standards
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CONSUMER REPRESENTATION IN STANDARDS DEVELOPMENT: LITERATURE REVIEW AND ISSUE IDENTIFICATION

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U.S. DEPARTMENT OF COMMERCE, Malcolm Baldrige, *Secretary*
NATIONAL BUREAU OF STANDARDS, Ernest Ambler, *Director*

FOREWORD

In February 1980, the Bureau of Medical Devices (BMD) of the Food and Drug Administration asked the National Bureau of Standards (NBS) for assistance in identifying and analyzing issues associated with U.S. government funding of consumer participation in voluntary standards activities. Since it was planning to endorse voluntary standards as part of its standards program for medical devices, BMD wanted to explore ways to facilitate consumer input to the standards development process. NBS's Office of Standards Information, Analysis, and Development (OSIAD), which had done a number of related studies on the impacts and regulatory use of voluntary standards, was happy to help BMD.

This literature review and issue identification paper is based on material prepared by OSIAD for BMD during the first stage of the consumer funding study. The information originally given to BMD has been updated and expanded for this publication.

It is hoped that the publication will give Federal agencies, standards organizations, and consumer groups deeper insights into the problems and benefits that might be associated with the development, operation, and evaluation of Government-sponsored programs to support consumer participation in standards-writing activities. For more information on this topic, you are invited to contact OSIAD.

Stanley I. Warshaw
Director
Office of Engineering Standards

ABOUT THE STANDARDS IMPACT ANALYSIS PROJECT

The Office of Standards Information, Analysis, and Development (OSIAD) is part of the NBS National Engineering Laboratory's Office of Engineering Standards. OSIAD has established a Standards Impact Analysis (SIA) project which has as its primary function providing NBS decisionmakers with information that will help them better understand the national and international standards systems and the economic, social, and other impacts of standards. It is hoped that this information will increase the effectiveness of NBS's participation in voluntary standards work and will contribute to the development of more rational and cost effective standards.

Functions of the SIA program include:

*Identifying needs for research: 1. on the impacts of standards; and 2. on standards systems and how they operate, and making these known to the academic, economic, and standards communities;

*Conducting or contracting for needed research of specific interest to NBS programs; and

*Maintaining close liaison with other NBS units and outside groups involved in standards impact or system assessment and developing a collection of studies in this area.

Some areas in which SIA has sponsored research are:

- Regulatory use of standards
- Standardization in foreign countries
- Economic principles applied to standard-writing
- Economics of the product certification industry
- Economic information on standards used in regulatory programs

For information on this report and other SIA studies, contact:

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I. INTRODUCTION

A. Purpose and Scope

The purpose of this report is to identify for possible future study by interested parties the major issues associated with consumer representation in the development of voluntary standards. Although this report focuses on the medical devices field, both the literature review and issue analyses are broadly applicable to the development of many kinds of voluntary standards.

The report does not address directly consumer participation in projects within a Federal agency to develop mandatory standards to be issued as Federal regulations. Instead, it addresses consumer participation in the private sector development of voluntary standards which may be incorporated into such regulations or used in lieu of such regulations.

The programs reviewed in Chapter III are almost entirely concerned with intervenor funding for proceedings conducted according to the Administrative Procedures Act. In the virtual absence of any Federal funding for consumer participants in voluntary standards development, these programs are what the agencies would consider as precedents for new program operations. Reviewing this body of related literature is an important means of determining the types of problems which will arise in new programs.

The issues summarized in Chapter VI were identified as follows. The most readily available literature was thoroughly reviewed. Based upon this review, individuals in Federal agencies, consumer organizations, and standards developing organizations were contacted and asked specific follow-up questions to eliminate identified information gaps to the extent feasible. All contacts were asked to recommend or supply further literature to be reviewed. The issues deemed by the parties involved to be the most critical to the successful implementation of a consumer participation funding program were then synthesized and delimited.

B. Background for the Case Study

The Medical Device Amendments of 1976 (PL94-295) establish a comprehensive system of regulation of medical devices intended for human use. In particular, the Amendments created new Sections 513 and 514 within the Food, Drug and Cosmetic Act, which is the basic enabling legislation for the Food and Drug Administration (FDA). Section 513 establishes three classes of medical devices to be regulated in terms of safety and effectiveness. Such regulation is in addition to requirements which affect all devices; that they are neither misbranded nor adulterated. Section 514 describes the development of performance standards for one of those three classes.

Class I devices are to be subject only to general controls over manufacturing processes because such general controls are deemed adequate to provide a reasonable assurance of safety and effectiveness. Class III devices are to be subject to premarketing approval by FDA for every specific brand of a device because their use is deemed to be critical to maintaining life and health.

The intermediate Class II devices are to be subject to performance standards: their uses are less critical than those in Class III, but good manufacturing practices are not deemed adequate to protect their users.

More than 1,200 medical devices have already been or are in the process of being classified by FDA as Class II devices. The task of developing safety and efficiency performance standards for so many devices is monumental. Even developing priorities for standards development has been a very time consuming and labor intensive effort.

With then current resource allocations, one FDA Bureau of Medical Devices (BMD) official had estimated that development of such performance standards solely within FDA would take in excess of 200 years to complete. Furthermore, that estimate was only for the initial development of performance standards. It did not include necessary periodic review and/or updating of the standards nor development of standards with respect to any future technological innovations in devices. Consequently, an alternative approach to strictly internal FDA development was sought to allow for the timely development of needed standards.

On February 1, 1980, FDA published in the Federal Register a notice of and a request for comments on such an alternative approach. Entitled "Voluntary Standards Policy for Medical Devices," the notice proposed "a policy for FDA involvement in the development, support, endorsement, and use of voluntary performance standards for medical devices." The FDA proposed "to endorse voluntary standards..." which device manufacturers would comply with in lieu of mandatory standards.

FDA explained the proposed Policy by stating that: "FDA believes that endorsing adequate voluntary standards will (1) encourage manufacturers, voluntary standards organizations, and other interested parties to continue to develop performance standards in their areas of expertise, (2) result in a greater number of performance standards being established more rapidly with fewer FDA resources than if only mandatory standards were issued, and (3) permit FDA to concentrate on the development of standards for Class II devices that are not the subject of adequate voluntary standards and are selected for their impact on the public health."

Related to the first point above, FDA recognized two important developments regarding all Federal interaction with voluntary standards developers. The first was the extensive interagency and public discussions that led to the publication of Office of Management and Budget (OMB) Circular A-119: "Federal Participation in the Development and Use of Voluntary Standards." It was signed by OMB Director McIntyre on January 17, 1980. The Circular is important because it provides for: (1) Federal agency reliance upon, and use of, voluntary consensus standards whenever feasible and appropriate as a means of reducing or eliminating redundant Federal efforts to develop and maintain in-house standards; (2) Federal agency participation in, and support of, standards developing activities of voluntary organizations; and (3) coordination of Federal agency participation to insure efficiency and consistency with Federal goals.

The second development was efforts by the Office of Special Assistant to the President for Consumer Affairs to encourage Federal agencies to increase both the magnitude and meaningfulness of consumer participation in agency decisionmaking, including decisionmaking regarding the development and use of standards. These efforts led to Executive Order 12160, which was signed by President Carter on September 26, 1979. Both of these government-wide developments will be more thoroughly discussed in Chapter II.

A key aspect of the proposed endorsement process is that it would require the FDA to insure that the developers of voluntary standards employ procedural and substantive safeguards similar to those FDA would have employed if it had developed the standard itself. These range from the needs for open meetings and documented decisionmaking to the need for the involvement of all interested parties including manufacturers, health care professional/institutional users, and consumers.

Assuring adequate consumer representation is very difficult due to the long-standing financial problems of both consumer organizations and voluntary standards developers. Consequently, FDA decided to explore ways to fund consumer representation. They soon found themselves faced with myriad questions that ranged from how to determine who can serve as a consumer representative to what administrative mechanisms could be used to fund such representation. This report represents the first stage of an effort to identify, evaluate, and make recommendations on specific steps that FDA could take to foster consumer participation in medical device standardization activities.

C. Definitions

For purposes of our research, we defined the terms "consumer" and "consumer representative" as follows:

> CONSUMER: A person who uses, or is the guardian of someone who uses, the product or services associated with the product for which a standard is being developed to satisfy personal needs and desires rather than to resell them or to produce other goods or services with them.
>
> CONSUMER REPRESENTATIVE: A person who is knowledgeable about the product for which a standard is intended and is either a consumer of the product or a person who has demonstrated skill in advocating one or more interests of consumers and who is not currently involved in the development, issuance, or enforcement of government regulations related to the same product.

Within the scope of the definition for a "consumer representative" of medical device users, members of the health care profession and former government employees may be classified as "consumer representatives" if they have demonstrated expertise in advocating one or more consumer interests and will be participating in the standards committee in their capacity as a "consumer representative."

In conducting our literature search, we reviewed other definitions of "consumer" which have been developed and used by the Federal government and by the standards community. None of those definitions proved totally satisfactory for the purposes of our research; however, they were used as a basis for developing the above definitions.

The primary definitions currently used for the term "consumer" are as follows:

> AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI) DEFINITION: "A person who uses goods or services to satisfy his personal needs and desires rather than to resell them or to produce other goods or services with them."
>
> EXECUTIVE ORDER 12160 DEFINITION: "any individual who uses, purchases, acquires, attempts to purchase or acquire, or is offered or furnished any real or personal property, tangible or intangible goods, services or credit for personal, family, or household purposes."
>
> IMPLEMENTING PROCEDURES FOR OMB CIRCULAR A-119 DEFINITION: "a user of the product or services for which a standard is developed who is not currently engaged in the manufacture or distribution of the same, or involved in the development, issuance, or enforcement of government regulations related to the same."

Another term which was frequently used in the literature on Federal consumer participation programs, is "interest." The literature did not specifically define this term; however, "interest" is defined by Funk and Wagnalls Standard College Dictionary to mean "involvement or concern in something"--a definition which appears to be compatible with the way Federal programs have used the term. In developing the definition for "consumer representative" it was recognized that there could be more than one "consumer interest."1/ Any person who would claim to represent all consumers would have to represent all the possible differing points of view, a task which is quite difficult if not impossible. Any definition of "consumer interest" that is not generic is unlikely to be of much practical use.

For these reasons, we have tried to avoid using or defining a generic "consumer interest." We have instead assumed that a consumer representative will advocate one or more different "consumer interests" such as those mentioned above. While it might be possible (and should be encouraged) for a consumer representative to attempt to explain some or all of the different "consumer interests" likely to be involved, in voting the representative cannot split his or her vote among opposing consumer interests.

Depending upon the reasons for which a standard is to be developed and upon the scope of the standard, one might need or desire to have a number of subcategories of "consumer." For instance, the following segment from the Winfree report, annotated in Chapter IV, discusses possible classifications:

1/See the Federal Trade Commission's discussion of this issue which is included in Chapter III of this report.

"As the society's efforts to involve an increasingly varied grouping of consumers continues, it becomes more apparent that a more specific categorization than consumer or "ultimate consumer" is needed. Just as the policy for consumer participation needs further refinement, the policy on consumer financing should be made more clear. This will only become more clear when more precise definitions of consumer are developed. The following consumer categories and definitions are offered to this end (Operating Procedures and Committee F-15 and National Policy on Standards were used as resources):

1. Ultimate Consumer
   Those whose primary affiliation is with the end use of materials, products, systems, or services, with which the committee is concerned.

2. Government Agency/Public Institution Representative
   Those whose primary affiliation is with a government agency or public institution whose regulatory powers or mission do not involve the products, materials, systems, or services with which the committee is concerned.

3. Consumer Advocate ("professional consumer")
   Those whose primary affiliation is with a consumer agency or organization either through employment or membership.

4. Academic Institution Representative
   Those whose primary affiliation is with an academic institution serving grades K-12.

5. Institutional or Governmental Purchasing Representatives
   Those whose primary affiliation is with a government agency or institution as a purchasing agent

6. Labor Consumer
   Those whose primary affiliation is as a representative of a labor organization either through employment or membership.

In striving for committee balance and consumer sounding board demographic cross sections, all of the above described kinds of consumers should be included..."

II. DEVELOPMENTS IN CONSUMER INVOLVEMENT IN GOVERNMENT AND STANDARDS ORGANIZATIONS

The recently established Federal Consumer Affairs Council noted: "There is no question that since the publication of Ralph Nader's Unsafe at Any Speed, which is sometimes cited as the dawn of the age of the consumer, government agencies have been more responsive to the needs of individual consumers than they were in the past." (Federal Register, Vol. 44, No. 238, December 10, 1979, p. 71104.) A number of developments have recently occurred in the Federal sector which have increased the efforts being made to involve and train the consumer as well as to provide reimbursement programs for public participation in Federal decision-making. In 1977, the Senate Governmental Affairs Committee completed a comprehensive study on public participation in regulatory agency proceedings and issued a report entitled, Study on Federal Regulation. In this report, the committee recommended that:

> "(u)ntil such time as general legislation for compensation of public participation costs is enacted, regulatory agencies should implement their own programs to compensate eligible participants in agency proceedings as appropriate..."

The Committee also recommended that Congress enact legislation.

Many legislative proposals to authorize payments have been introduced in Congress in recent years. However, the support for these measures has diminished to some degree because of stringent budget conditions. In recent years, the Toxic Substances Control Act, the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act, and the Foreign Relations Authorization Act did provide the Environmental Protection Agency (EPA), the Federal Trade Commission (FTC) and the State Department with explicit authority to establish reimbursement programs. Many other agencies have acted on their own initiative to establish increased opportunities for public participation. FDA has established a program based on authority conferred by the Agriculture, Rural Development, and Related Agencies Act for Fiscal Year 1979 which contained FDA's appropriation for that year. These programs have, however, been carefully scrutinized by the Congress in light of tight budget conditions. Some agencies (e.g., the Department of Transportation) have sustained serious program cuts, while others have not been able to secure initial funding for their public participation compensation programs. While Departments such as Agriculture continue to develop and implement new programs, Congress is carefully reviewing the management and achievements of existing programs and plans for new programs. Success in securing funding requires detailed planning, effective program management, and thorough documentation to the Congress of need and utility.

In 1979, the Commission on Law and the Economy of the American Bar Association published a study entitled, "Federal Regulation: Roads to Reform," which included the following recommendation:

> "The Commission supports the following resolution of the American Bar Association, which calls for 'The payment by government of attorneys' fees and other expenses, under proper limitations and controls, in

> administrative proceedings and in the judicial review of such proceedings when the availability of such fees and expenses is necessary to assure the presentation of positions which deserve full and fair consideration in the public interest and would otherwise not be presented.' Congress should appropriate funds for this purpose."

The report noted that individuals who represent currently under- represented interests "...have special difficulties in financing their participation, partly because of the cost of raising funds from a large number of donors..., and partly because some are unwilling to contribute in the hope that others will bear the cost..." Participation in a standards development project which can span several years can be an expensive, and perhaps too expensive a process to allow many individual consumers and organized consumer groups to participate effectively. If these standards are later to be used by a Federal agency as part of its regulatory program or consciously in lieu of regulation, then these interests may end up not being adequately represented.

There also have been a number of presidential initiatives to increase consumer participation as well as to increase the use of voluntary standards by Federal agencies. For instance, OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Standards, promotes the use of voluntary standards by Federal agencies. It includes as a pre-condition of Federal participation in such efforts that a serious attempt be made to achieve "broadly-based representation" on the voluntary standards bodies.

In the case of standards which are to be used within the context of a regulatory program, the opportunity for early participation implies that interested parties be given an opportunity to participate in the standards development process itself.

In September 1979, President Carter signed Executive Order 12160, Providing for the Enhancement and Coordination of Federal Consumer Programs, designed to improve consumer participation in agency decisionmaking. The Order requires that:

> "Agencies establish procedures for the early and meaningful participation by consumers in the development and review of all agency rules, policies, and programs."

This Order also includes provisions to draw attention to consumer participation including a "consumer program exhibit in (each agency's) yearly budget submission to the Office of Management and Budget" and oversight of consumer programs by a Consumer Affairs Council comprised of representatives from the 12 cabinet-level departments. By Executive Order 12265 of January 15, 1981, President Carter increased the membership of the Council from 12 to 24.

There is evidence of Presidential and Congressional support of increased public participation in government decisionmaking. However, current budget conditions are exerting pressures on agencies to control the growth and development of financial compensation programs for consumers and other interested members of the public.

The standards organizations have also been active in promoting consumer participation. A number of them (including the American National Standards Institute (ANSI), the American Society for Testing and Materials (ASTM), and Underwriters Laboratories (UL)) have made significant efforts to increase the involvement of consumers in all phases of the voluntary standards development process. ASTM is currently in the second year of funding the National Consumers League to systematically provide consumer representation on committees writing standards which directly impact on consumers.

The following three chapters offer some insights into the events and writings which are currently shaping consumer participation in the decisionmaking process of the Federal Government and the voluntary standards organizations. Each of these chapters consists of an overview, which may serve as an Executive Summary of the subject, plus an annotated bibliography providing details from the available literature.

III. REFERENCES RELATED TO FEDERAL PUBLIC PARTICIPATION PROGRAMS

A. Overview

This section of the paper contains information on public participation programs in the Federal decisionmaking process. Federal agencies use the term "public" rather than "consumer" because such participation programs are intended to promote full and fair representation by all affected "interests". These "interests" may include groups other than consumers, such as small businesses and non-profit organizations. Particularly noteworthy is the discussion by the Federal Trade Commission on why no participants can represent the "consumer interest" as they define it.

The strong and weak points of Federal "public participation" funding programs are described below. References are organized by agency, each of which either had compensation programs, other interesting ideas or procedures for facilitating participation, or specific reasons for not having public participation programs. The abstracts do not attempt to describe each agency's program in detail; instead, they highlight facets of the program which may be of interest to agencies wishing to develop a compensation program for consumer participation. More detail on each specific agency's program or procedures can be found in the references listed.

All public participation compensation programs incorporate in their selection procedures some form of the Comptroller General's decisions on eligibility criteria (see references on page 31). These are: (1) that a participant must represent an interest that can reasonably be expected to contribute substantially to a full and fair determination of the issues involved; (2) that the size of the participant's economic interest in the proceeding is small compared with the participant's cost for effective participation; and (3) that the participant does not have sufficient financial resources available for effective participation in the absence of financial compensation. In addition, all agencies use other factors to select among those who meet these eligibility criteria.

In most programs, agency staff select individuals to be compensated. The exceptions are the Consumer Product Safety Commission's "offeror" process and the Department of Energy's solar standards development projects with two standards organizations. CPSC may select an outside group, or "offeror", to develop a specific standard, and the "offeror" then chooses compensated individuals. For the DoE projects, the standards organizations make the selection with the assistance of a consumer group; oversight responsibility is maintained by DoE.

Most programs appear to have had funding problems. Some have been unable to secure initial funding; others have had their funding cut; and still others are inadequately funded. A few agencies noted problems with getting consumers to participate on a regular basis and have resorted to paying a stipend, usually $100 per day, in addition to reimbursement for travel and per diem costs.

Another common aspect of public participation programs is that they usually provide orientation literature for participants. The Department of Energy's Citizen Participation Manual is particularly impressive. It contains valuable advice for agency staff members attempting to start or maintain a public participation program.

Section C of this chapter includes abstracts of other documents that may be of interest to those involved in establishing or analyzing compensation programs. These documents are not related to any one agency's program and are grouped in alphabetical order. Of particular interest is the study done on public participation by the Senate Committee on Governmental Affairs as part of an overall Study on Federal Regulation, as well as E.O. 12160, Providing for Enhancement and Coordination of Federal Consumer Programs. Both documents support the need for increased participation in agency decision-making, and the Senate document further supports the desirability of funding such participation. The article, "Intervenor Funding: Public Participation in Rulemaking," is an informative discussion of the differing points of view towards the need for and desirability of funding participation.

B. Annotated Bibliography of Specific Federal Public Participation Programs

THE CIVIL AERONAUTICS BOARD's (CAB) FINANCIAL COMPENSATION PROGRAM

Civil Aeronautics Board (CAB). Applying for Compensation for Participation in CAB Proceedings. Washington, D.C.: CAB, January 1979.

_____. Compensation of Participants in Board Proceedings. 14 CFR 304.

****

After being operational for approximately 9 months, CAB's financial compensation program was terminated by Congress in P.L. 96-131, (93 Stat. 1023) on November 30, 1979. A description of their program prior to FY 1980 follows.

The final rule for CAB's compensation program was adopted on October 26, 1978, and became effective November 28, 1978. A number of supporting comments were received on the proposed program. Formal opposition to the program was expressed by:

- the Air Transport Association of America
- National Legal Center for the Public Interest
- Missouri Department of Transportation
- Senator Howard S. Cannon
- Chamber of Commerce of the United States
- National Association of Manufacturers

The opponents of the program stressed that it was "unnecessary, impracticable to administer, and an improper and illegal use of public money." The CAB, however, felt that authority for the program was implicit in the Federal Aviation Act and explicit in their appropriations act for FY 1979. The Conference Committee's report accompanying the appropriations act provided for expenditures not to exceed $150,000 for "a 1-year demonstration project involving the participation of public interest groups and individuals in the Board proceedings."

The Aviation Consumer Action Project (ACAP), Common Cause, and the Americans for Democratic Action favored an "Evaluation Committee" composed of the Managing Director, the General Counsel, and the Director of the Office of Economic Analysis to make the selections for compensation. Consumer Federation of America and Public Citizen favored creation of a separate office. Because of funding limitations and because the approach appeared workable, the committee approach was chosen.

Appeals from disapproved applicants for discretionary review by the Board were allowed if filed within 10 days of disapproval. Applications, decisions, and staff correspondence were placed in the CAB Public Reference Room. Communications between the Committee and those staff members involved in the proceeding were to be limited to whatever was necessary for the Committee to ascertain whether the applicant's presentation as described in his or her application would likely duplicate that of the staff.

The Evaluation Committee was also authorized to contact other Federal agencies regarding the effectiveness of the applicant's contribution in other agency proceedings. The CAB required applicants to list the proceedings of other Federal agencies in which they participated in the preceding year and the amount of any compensation that they received. Americans for Democratic Action objected to this requirement, but the CAB felt that it was useful in evaluating whether the other agencies received good value for what they paid.

Eligibility criteria were:

> "(1) The applicant must represent an interest whose representation can reasonably be expected to contribute substantially to a full and fair determination of the proceeding, in light of the number and complexity of the issues presented, the importance of public participation, and the need for representation of a fair balance of interests;
> (2) Participation by the applicant must be reasonably necessary to represent that interest adequately;
> (3) It must be reasonably probable that the applicant can represent the interest competently within the time available for the proceeding;
> (4) The applicant does not have available, and cannot reasonably obtain in other ways, enough money to participate effectively in the proceeding without compensation under this part (304); and
> (5) The applicant's economic interest in the outcome of the proceeding is small in comparison with the burden of effective participation, except that if the applicant is a group or organization, the Committee need only find that the economic interest of a substantial

majority of its individual members is small compared with the burden of effective participation."

The CAB also noted that "(a)n individual's ability to participate without compensation will depend not only on his or her own income, but on the cost of participating in the particular case."

The Committee was able to waive the "small economic interest" provision if the applicant's participation would have been exceptionally important.

Additional selection factors for eligible applicants that the Committee considered in reviewing the applications of eligible candidates were:

(1) The applicant's experience and expertise in Civil Aeronautics Board matters generally and in the substance of the proceeding particularly;
(2) The applicant's prior general performance and competence;
(3) Evidence of the applicant's relationship to the interest he or she seeks to represent;
(4) The specificity, novelty, relevance, and significance of the matters the applicant proposes to develop and present; and
(5) The public interest in promoting new sources of public participation.

Three applicants were funded during the program's operation. Two of the funded applicants were considered to have made significant contributions to the proceedings.

THE CONSUMER PRODUCT SAFETY COMMISSION'S (CPSC) FINANCIAL COMPENSATION PROGRAM

Consumer Product Safety Commission (CPSC). CPSC Financial Compensation Application Form.

_____. "Financial Compensation of Participants in Informal Rulemaking Proceedings." Proposed Rule: Federal Register, Volume 42, No. 56, Wednesday, March 23, 1977.

_____. "Financial Compensation of Participants in Informal Rulemaking Proceedings." Interim Rule: Federal Register, Volume 43, No. 105, Wednesday, May 31, 1978.

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Funding for CPSC's program for funding public participation in informal rulemaking proceedings was cut from their FY 1981 appropriation. The above documents describe CPSC's program prior to FY 1981. These documents do not cover financial compensation for costs incurred by "offerors" who are selected by CPSC to develop proposed consumer product safety standards, nor for other standards development proceedings authorized under Section VII of the Consumer Product Safety Act.

CPSC used the criteria established by the Comptroller General's decisions to determine the eligibility of participants for compensation.* To select among those who were eligible, CPSC used three selection criteria:

1. The importance of the proceeding;
2. The need for representation of particular interests or viewpoints; and
3. The expected representation of particular interests or viewpoints in the absence of Commission funding.

When the Commission anticipated that financial compensation to participants was necessary in a given proceeding, it published an announcement to that effect in the Federal Register. The Commission, however, also considered unsolicited applications. Items eligible for compensation were outlined in the Federal Register notices. The participant was paid upon submission of an itemized voucher. All pertinent records of a participant who received compensation must be kept for a period of three years and are subject to audit by the Commission and the General Accounting Office. This requirement was the same for all agencies operating funding programs.

Even though the documents refer to consumer participation, only "participant" is defined, namely as: "any interested individual, group of individuals, public or private organization or associates, partnership, or corporation who or which is taking part or intends to take part in a Commission proceeding." The eligibility criteria were used to eliminate representatives of industry with a major stake in the outcome of the proceedings.

The budget for the program in FY 1980 was $50,000. In discussions with CPSC staff, they noted that CPSC had no problem in obtaining qualified participants. The Public Participation Committee, which made the selections, tried to obtain different types of general interest participants (e.g., educators, technical experts, and consumer representatives) in proceedings.

Objections to the program were voiced by the National Legal Center for the Public Interest, the Grocery Manufacturers of America, the Chamber of Commerce of the United States, The Proprietary Association, and the Pacific Legal Foundation. Their objections include the following:

1. It will be impossible to choose fairly among the groups and individuals requesting funding.
2. Funding is not only very expensive but is not needed because the "legal public interest movement is well represented and well funded."
3. The Commission lacks the legal authority for the program.
4. In view of the bills pending in Congress to provide specific statutory authority and financing for compensation programs in numerous Federal agencies, the Commission's program is premature.
5. The program "would invite dilatory litigation challenging the agency's exercise of its discretion in granting or denying funds."
6. The program "raises ominous possibility of agency co-option of 'public interest' participants by application of the agency's discretion as to whom funds will be made available."

*See page 10 of this report.

The CPSC, however, did not feel that these objections were adequate to abandon the program. The Federal Register notices regarding the program did contain a cautionary statement that:

> For consumer participation to be effective, it must be technically competent and presented in such a way that the Commission can rely on it to balance information and views from the regulated industry.

CPSC also held that they had adequate authority to undertake the program and that the U.S. Court of Appeals for the Second Circuit's decision in Greene County Planning Board v. Federal Power Commission referred to in some of the objections was not binding on any Federal agency except possibly the Federal Energy Regulatory Commission which took over the authority and functions of the Federal Power Commission. The decision held that the Federal Power Commission lacked the necessary statutory authority to pay counsel fees for intervenors in a licensing proceeding. The Comptroller General of the United States in decisions dated February 19, 1976, and May 10, 1976, held that the Commission has the authority to provide compensation to those who cannot afford to participate but whose participation is necessary to full and fair proceedings.

The Consumer Product Safety Commission's program did allow small business interests to be funded.

FINANCIAL COMPENSATION UNDER THE CONSUMER PRODUCT SAFETY COMMISSION'S "OFFEROR" PROGRAM

Blechschmidt, Carl E. "Miniature Christmas Tree Light Standard Development Agreement." Memorandum dated June 7, 1977.

Consumer Product Safety Commission (CPSC). Consumer Product Safety Act: Public Law 92-573. 15 USC 2051-2081.

_____. Handbook and Standard for Manufacturing Safer Consumer Products. Washington, D.C.: CPSC, June 1975 (Revised May 1977).

_____. Subchapter B- Consumer Product Safety Act Regulations: Part 1105 Submission of Existing Standards; Offers to Develop Standards; and the Development of Standards. 16 USC 1105.

_____. "U.S. Consumer Product Safety Commission." Washington, D.C.: CPSC, October 1979. (pamphlet)

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Development of a consumer product safety standard under the "offeror" program is authorized under Section 7 of the Consumer Product Safety Act and begins with the publication of a notice in the Federal Register which will:

"1. identify the product and the nature of the risk of injury associated with the product;
2. state the Commission's determination that a consumer product safety standard is necessary to eliminate or reduce the risk of injury;
3. include information with respect to any existing standard known to the Commission which may be relevant to the proceeding; and
4. include an invitation for any person, including any State or Federal agency (other than the Commission), within 30 days after the date of publication of the notice... to submit to the Commission an existing standard as the proposed product safety standard or... to offer to develop the proposed consumer product safety standard."

If it accepts an offer to develop a standard, the Commission may contribute to the offeror's cost in developing the standard, including reimbursement for the costs incurred by consumer participants.

The Commission may contribute to such costs in any case where it determines:

"1. That a contribution is likely to result in a more satisfactory standard than would be developed without such a contribution; and
2. That the offeror is financially responsible."

In addition the offeror must submit:

"1. A request for a specific contribution with an explanation as to why the contribution is likely to result in a more satisfactory standard than would be developed without a contribution;
2. A statement asserting that the offeror will employ an adequate accounting system (one in accordance with generally accepted principles) to record standard development costs and expenditures; and
3. A request for an advance payment of funds if necessary to enable the offeror to meet operating expenses during the development period."

As of April 1981, CPSC had funded the development of seven standards through the offeror process.

The Commission has an informal guideline that one third of the standards-development committee should be consumer representatives. Half of these representatives should be technical experts and half non-technical experts. The offeror selects the consumers. Because of the difficulty in getting consumers to participate consistently in standards development activities, the CPSC allows consumers to be paid up to $100 per day plus travel and per diem expenses. CPSC pays the offeror, who in turn pays the consumers. Small business representatives have not been funded under this program, though they have been funded for the in-house development of standards. The budget for the offeror program comes out of operating funds and is not shown as a separate line item.

CPSC does not evaluate the contribution or quality of the consumer participation as such. They also do not regard standards writing committees as Federal advisory committees, nor do they regard funded consumers as Federal employees.

Their method of securing the services of an offeror is done through a cooperative agreement, as opposed to a contract or grant. CPSC also provides the committees with such support services as are mentioned in its regulations and are stated in the cooperative agreement.

Section 7 activities were not cut from CPSC's FY 1981 appropriations. CPSC also has the authority under Section 7 to develop standards in house and to provide funding for participation on these committees by selected members of the public.

THE DEPARTMENT OF AGRICULTURE'S (USDA) FINANCIAL COMPENSATION PROGRAM

Department of Agriculture (USDA). "Reimbursement of Participants in Rulemaking Proceedings." Federal Register. Vol. 45, No. 17, Thursday, January 24, 1980, pp. 6020-6026.

_____. Reimbursement of Participants in USDA Rulemaking Procedures: A Handbook for Applicants. Washington, D.C.: Office of Budget, Planning and Evaluation, USDA.

_____. "Secretary's Memorandum No. 1955." Washington, D.C.: USDA, September 25, 1978.

Juers, Linley E. "Public Participation Plans." Memorandum dated August 16, 1979.

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In March 1979, USDA proposed regulations to govern reimbursement to selected groups and individuals who participate in agency proceedings. The final regulation appeared in the Federal Register on January 24, 1980, and became effective February 25, 1980. The program does not have a line item budget, and funds will come out of operating funds. The head of the USDA agency(s) conducting the rulemaking will make the determination as to whether such funding will be available. Selection of participants for compensation will be made by a 3-member Evaluation Board composed of staff other than staff of the USDA agency(s) involved in the proceeding.

The March 1979 proposal received over 150 comments. Most of the negative comments were concerned with the stringency of the disclosure requirements. Other negative comments included:

1. The degree of public support for a viewpoint could be measured by the amount of money and resources that an organization could raise to make an appearance. Consequently, there is no need for reimbursement.
2. Reimbursement will create additional burdens and delays in the administrative process and would add to the cost of regulations.
3. Potential abuses under the program could involve agency favoritism of certain views, use of government funds where private funding could be

used, and the use of the program by an agency to develop new advocates.

The regulation does not define "consumer" but, rather, uses the term "applicant." "'Applicant' means any person requesting compensation under this part to present views as a participant in a rulemaking proceeding, including individuals or any profit or non-profit group, association, partnership, or corporation. This does not include a local, state or Federal agency."

Eligibility criteria for applicants are:

"1. The applicant has demonstrated that it does not have sufficient resources available to participate effectively in the proceeding in the absence of an award under this part. In making this determination, the Evaluation Board may consider, but is not limited to, the following factors:

   i. The amount of an applicant's assets that are firmly committed for other expenditures;
   ii. The amount of its own funds the applicant will spend on participation; and
   iii. Whether an appearance of being impecunious is achieved by establishing a sham organization to receive reimbursement under this part or other similar Federal reimbursement programs.

2. Except for expert witnesses whose technical expertise is required, the applicant is a resident of the locality to be affected, and seeks to represent an interest that is not otherwise adequately represented.

3. The applicant's participation would, or could reasonably be expected to, contribute substantially to a full and fair determination of the issues involved in the proceeding, taking into consideration the following factors:

   i. The ability of the applicant to represent in a timely and competent manner the interest it espouses, including the applicant's or its consultant's or attorney's experience and expertise in the substantive area at issue in the proceeding;
   ii. How the applicant's interest is affected or evidence of the applicant's relation to the affected interest it seeks to represent."

Costs which are reimbursable are defined in the "Handbook for Applicants" and are similar to those of other agencies.

THE DEPARTMENT OF COMMERCE'S (DOC) FINANCIAL COMPENSATION PROGRAM

United States Regulatory Council. "Appendix I--Public Participation in the Federal Regulatory Process." Federal Register, Vol. 45, No. 228, pp. 78069-71.

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DOC has several limited funding programs for public participation. Although the Department's General Counsel has determined that in such instances there are no statutes that forbid such a funding program, Department funds may be used by an agency only when public participation is found necessary and when lack of funding would preclude an individual from participating.

The National Marine Fisheries Service (NMFS) in the National Oceanic and Atmospheric Administration (NOAA) reimburses public participants under its Fisheries Financial Assistance Program. The Administrator of NOAA may provide compensation for "reasonable attorneys' fees, fees and costs of experts, and other costs of participation incurred by eligible participants in any NOAA proceeding involving a hearing in which there may be public participation." Rules governing this program can be found in 15 CFR Part 904. The National Telecommunications and Information Administration (NTIA) is currently developing rules to implement a public participation program. Other DOC agencies may fund public participants on an ad hoc basis.

THE DEPARTMENT OF ENERGY'S (DOE) FINANCIAL COMPENSATION PROGRAM

Department of Energy (DOE). Citizen Participation Manual (DOE Order 1210.1). Washington, D.C.: DOE, August 13, 1979.

_____. The Energy Consumer. Washington, D.C.: Office of Consumer Affairs, DOE, published monthly.

_____. "Improving Government Regulations; Semiannual Agenda of Regulations." Federal Register, Vol. 44, No. 219, Friday, November 9, 1979, pp. 65274-65287.

_____. "Improving Government Regulations; Semiannual Agenda of Regulations." Federal Register, Vol. 45, No. 214, Monday, November 3, 1980, pp. 72886-72898.

_____. Procedures for the Development and Analysis of Regulations, Standards, and Guidelines (DOE Order 2030.1). Washington, D.C.: DOE, December 18, 1978.

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DOE has been prohibited by Congress from providing direct funding for public participation in any Economic Regulatory Administration proceedings. As noted by DOE in the November 3rd issue of the Federal Register, "DOE has determined to stay actions on these regulations (public participation funding) pending prior congressional approval " Therefore, no direct funding program exists. The Citizen Participation Manual (Manual) does give excellent information for setting up participation programs. It includes information on (1) planning public meetings; (2) seating arrangements; (3) involvement techniques; (4) public participation budget estimates; (5) planning and implementing surveys

and questionnaires; (6) evaluating public participation; (7) recording, summarizing, and evaluating public comments; and (8) preparing the public to participate.

The Manual notes that:

> "Public participation takes time. Planning and implementation of any event or series of events can take as long as 7 months - and in no case less than 3 months."

It also notes that:

> "Mailing lists on virtually all categories of publics are available commercially. Costs begin at approximately $40 per thousand names, with costs increasing depending on the requirement for special listings and mailing labels."

The Manual also gives budget estimates for other types of costs.

The Department of Energy does have contracts with the Council of American Building Officials (CABO) and the American Society for Testing and Materials (ASTM) to facilitate the development of a "model" solar energy code. Guidelines issued for use of these funds include provisions for funding consumer participation on the ASTM Committee E-44: Solar Energy Conservation. The Solar Lobby (a consumer-type organization) assists in obtaining consumer participation for this committee. Oversight responsibilities for consumer participation funding rest with DOE.

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' (HHS) FINANCIAL COMPENSATION PROGRAM

Department of Health and Human Services (HHS). Demonstration Project to Assist Those Wishing to Comment on Proposed Regulation Implementing the Adoption Assistance and Child Welfare Act of 1980, Federal Register, Vol. 45., No. 244, Wednesday, December 17, 1980.

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HHS is considering the development of regulations regarding funding public participants within the Department. As a first step, HHS is undertaking a demonstration project to assist qualified applicants with the costs of commenting on regulations for carrying out Title I of the Adoption Assistance and Child Welfare Act of 1980 (P.L. 96-272). According to the December 17, 1980, Federal Register statement announcing the program, "(a) major purpose of this demonstration project is to learn whether financial assistance will achieve a more complete discussion of significant issues and a greater diversity of oral and written comments on proposed regulation."

An Evaluation Board consisting of representatives from the following six program areas--Intergovernmental Affairs, Legal, Management and Budget, Public

Affairs, Planning and Evaluation, and Consumer Affairs--will make the selections. The eligibility criteria will be:

"1. The information the applicant plans to present will help the Department to decide the issues in these proposed regulations.
2. The applicant represents an interest that otherwise might not be heard.
3. The applicant cannot otherwise afford the costs of going to a regional meeting or of preparing written comments."

Applicants can be reimbursed for travel, lodging, and meals as well as certain costs of preparing written comments. Applicants selected will be notified in writing and will receive an approved budget. Applicants who are not selected will be notified as to the reasons for nonselection.

THE DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT'S (HUD) FINANCIAL COMPENSATION PROGRAM

United States Regulatory Council. "Appendix I--Public Participation in the Federal Regulatory Process." Federal Register, Vol. 45, No. 228, pp. 78072-78073.

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HUD published an announcement of a proposed rulemaking in the Federal Register on March 4, 1980, regarding funding public participation in departmental proceedings. Approximately 40 comments were received on the proposal. HUD is evaluating these comments and has not made a decision on whether to proceed in the rulemaking.

THE ENVIRONMENTAL PROTECTION AGENCY'(EPA) FINANCIAL COMPENSATION PROGRAM

Environmental Protection Agency. "Proposed Policy on Public Participation." Federal Register, Vol. 45, No. 85, Wednesday, April 30, 1980, pp. 28912-28919.

_____. "Responsiveness Summary and Preamble on Public Participation Policy." Federal Register, Vol. 46, No. 12, Monday, January 19, 1981.

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EPA had proposed a pilot program in the April 30, 1980 issue of the Federal Register to fund participation in several rulemaking activities. Congress, in its action on EPA's 1981 appropriation, prohibited the use of EPA funds for financial assistance to members of the public to allow participation in regulatory or adjudicatory proceedings. Other types of public participation

funding such as reimbursement for witnesses at public hearings are still permitted by Congress. According to the January 19, 1981, issue of the Federal Register, the agency expects to continue to fund non-regulatory, non-adjudicatory participation in FY 1981. Assistant Administrators, Office Directors, and Regional Administrators can provide such funds to outside individuals and organizations as they deem "appropriate and essential for achieving program goals." The EPA managers authorized to release such funds are to make such awards based on the following criteria:

"(1) whether the activity proposed will further the objectives of this Policy (spelled out in the January 19th notice);
(2) whether the activity proposed will result in the participation of interests not adequately represented;
(3) whether the applicant does not otherwise have adequate resources to participate; and
(4) whether the applicant is qualified to accomplish the work.

"These are the primary tests for public participation financial assistance. From among those who meet these tests, the Agency will make special efforts to provide assistance to groups who may have had fewer opportunities or insufficient resources to participate."

THE FEDERAL COMMUNICATIONS COMMISSION'S (FCC) FINANCIAL COMPENSATION PROGRAM

Federal Communications Commission. "A Guide to FCC Information: Reprinted by FCC Consumer Assistance Office." Washington, D.C.: Federal Communications Commission, March 1980.

_____. "A Guide to Open Meetings." Washington, D.C.: Federal Communications Commission. (Pamphlet with general information on open meetings.)

_____. "FCC Actions Alert." Washington, D.C.: Federal Communications Commission. (Weekly summary of Commission actions.)

_____. FCC Feedback. Washington, D.C.: Federal Communications Commission. (A Consumer-oriented summary of major FCC proposals).

_____. "How FCC Rules are Made." Washington, D.C.: Federal Communications Commission (Reprinted from the FCC Communicator, September 1975).

_____. "Reimbursement of Expenses for Participation in Commission Proceedings." Federal Register. Notice of Inquiry: Vol. 43, No. 138, Tuesday, July 18, 1978, pp. 30834-30840. Notice of Proposed Rule Making: Vol. 45, No. 12, Thursday, January 17, 1980, pp. 3335-3349.

_____. "The Public and Broadcasting: A Procedure Manual." Federal Register; Vol. 39, No. 173, Thursday, September 5, 1974, pp. 32288-32296.

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The above reference materials can be used by participants in rulemaking proceedings of the agency. The FCC is considering the creation of a financial compensation program for public participation, but does not have such a program at this time.

The FCC published a Notice of Inquiry for such a program on July 18, 1978, in the Federal Register. A Proposed Rule was published on January 17, 1980. Comments on the proposed rule were due May 23, 1980. According to Erika Jones, Consumer Assistance Office, FCC, the FCC has requested funding for this program from Congress but does not expect to be funded during FY 1981. The program, if funded, will be administered from the Consumer Assistance Office and will apply to informal rulemaking only, not licensing. The proposed rule also noted that in regards to FCC's authority to conduct such a program:

> "We believe that if we receive an appropriation from Congress, there can no longer be any question concerning our legal authority. Although we have decided to seek an appropriation before establishing a program, we believe that even absent such an appropriation we possess statutory authority to establish a reimbursement program."

The proposed rule also noted:

> "We wish to emphasize that under our proposed (eligibility) test small businesses that are unable to finance their own participation would be eligible to receive financial assistance if they can contribute substantially to the proceeding."

Selection will be made by an evaluation panel composed of the Chief, Office of Plans and Policy; the Chief, Office of Science and Technology; and the General Counsel, or their respective delegates. The views of staff members involved in the proceeding will be considered by the panel. The FCC also noted that staff recommendations should be in writing where possible and available to the public. The FCC also intends to prepare a written determination on the disposition of each application which explains the reasons for the panel's decision.

THE FEDERAL ENERGY REGULATORY COMMISSION'S (FERC) FINANCIAL COMPENSATION PROGRAM

United States Regulatory Council. "Appendix I--Public Participation in the Federal Regulatory Process." Federal Register, Vol. 45, No. 228, pp 78081-78082.

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Even though Congress established conditions under which qualified intervenors could be compensated by FERC under the Public Utility Regulatory Policy Act of 1978, it has not provided any funding for such a program and has included an

absolute prohibition on the use of FERC FY 1980 and 1981 appropriations to fund public intervention.

THE FEDERAL TRADE COMMISSION'S (FTC) FINANCIAL COMPENSATION PROGRAM

Administrative Conference of the United States (ACUS). "Recommendation 79-5: Hybrid Rulemaking Procedures of the Federal Trade Commission--Administration of the Program to Reimburse Participants (Adopted December 14, 1979)." Washington, D.C.: Administrative Conference of the United States, 1979.

Federal Trade Commission (FTC). "Applying for Reimbursement for FTC Rulemaking Participation." Washington, D.C.: Office of the General Counsel, FTC.

_____. "Rulemaking and Public Participation under the FTC Improvement Act." Washington, D.C.: Office of the General Counsel, FTC.

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FTC's program has been operating since 1975. Authority for the program is contained in section 202(h) of the Federal Trade Commission Improvement Act (15U.S.C.57A). Recently, Congress has directed the FTC to modify its program to insure that all those who traditionally are represented in rulemakings have the means to make adequate presentations. Individuals, citizens groups, single businesses, and trade associations are eligible for funding. The General Counsel, who has no responsibility for the rulemaking proceedings, makes all decisions as to who is eligible for reimbursement. The Special Assistant to the General Counsel administers the program.

FTC uses the term "interest" or "any person;" it does not define "consumer interest" because:

> "...(A) proposed rule might raise costs and prices as the price of preventing certain deceptive practices. At least three distinct consumer interests may arise in such a case: (1) Those who want the protection and believe it worth the increase in price; (2) those who prefer to look out for themselves and buy more cheaply; and (3) those who would be priced out of the market completely by the increase, therefore deriving no benefit from the rule. It is unclear how a group representing "consumers" can encompass all three points of views... Or, groups may agree on a consumer protection goal but be opposed in their assessment of the best way to obtain it."

For these reasons, FTC had a stated policy of "giving preference to applicants who define their interest or point of view with greater specificity" than broad consumer interest.

To be eligible applicants must show that:

(1) Representation of the interest would be necessary for a fair determination of the rulemaking.
(2) The interest would not otherwise be adequately represented in the rulemaking.
(3) Their financial situation would not otherwise allow them to participate effectively in the rulemaking.

In addition, the aggregate amount of compensation paid in any one fiscal year to any individual, business, or organization may not exceed 25 percent of the aggregate amount paid to all persons in that fiscal year. The FTC is also required to set aside 25 percent of its participation funds for small businesses whose views might otherwise not be adequately represented. This amount is available to reimburse only those small businesses (and their trade associations) who meet the conditions for the program and would be regulated by the proposed rule involved.

The FTC may provide compensation for "reasonable attorneys' fees, expert witness fees, and other costs of participating in a rulemaking proceeding." The participant may also be reimbursed for "(s)alaries, travel, printing and document reproduction, and other operating expenses the Bureau deems necessary to effective participation." The FTC has the authority to make advance payments up to 50 percent of the maximum approved budget.

In selecting among eligible participants, FTC uses the following factors in their deliberations:

"1. Point of view not already represented.
2. Specificity of interest, issues to be presented.
3. Relationship between the applicant and the interest he wishes to represent.
4. Support from the constituency the participant represents.
5. Experience and expertise of the applicant related to the subject area.
6. Experience in trade regulation matters generally.
7. General performance and competence to carry out activities related to participation.
8. Willingness of the participant or represented interest to contribute to the cost of participation."

THE FEDERAL RESERVE BOARD'S (FRB) FINANCIAL COMPENSATION PROGRAM

Board of Governors of the Federal Reserve Board. Rules of Organization and Procedure of the Consumer Advisory Council. 12 CFR 167.1-6, Effective November 1, 1976.

_____. Rules of Organization: Rules of Procedure. 12 CFR 262.3-6, 1979.

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The Federal Reserve Board has a Consumer Advisory Council to advise and consult with it on consumer related matters. The Board tries to achieve a fair representation of both creditors and consumers on the Council. Council members are selected by the Board, and receive pay not to exceed $100 per day as well as transportation and subsistence. The Council consists of not more than 30 members appointed for 3-year terms. Meetings are to be held at least once a year and may be held more frequently at the call of the Board.

THE FOOD AND DRUG ADMINISTRATION'S (FDA) FINANCIAL COMPENSATION PROGRAM

Food and Drug Administration. "Reimbursement for Participation in Administrative Proceedings." Federal Register, Proposed Rule: Vo. 44, No. 75, Tuesday, April 17, 1979, pp. 23044-23056. Final Rule: Vol. 44, No. 199, Friday, October 12, 1979, pp. 59174-59189.

Consumer Update. A monthly publication put out by the Office of Consumer Affairs, FDA.

Grant, Alexander. "Increasing Public Participation in Government." Cosmetic Technology, Vol. 2, No. 1, January 1980, pp. 20-23.

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In FY 1979, FDA established a 1-year trial program for funding consumer, small business, and other public participants in certain FDA administrative proceedings. Selection of applicants was to be made by an Evaluation Board composed of agency staff and chaired by the Special Assistant for Consumer Affairs. Applicants were required to file an "Application for Reimbursement" within 25 days after the date of publication in the Federal Register of the notice of hearing. The information to be provided on the application form included:

- Information on the organization's corporate structure, general purposes and tax structure.
- Descriptions of any previous affiliations with FDA or with any person who has produced or produces a product subject to FDA regulation.
- A description of how the proceeding will affect the applicant economically, socially with respect to health or safety, or otherwise and an explanation of why the applicant would be an appropriate representative of other persons similarly affected.
- A description on any income-producing relationship between the applicant and any person or organization having an economic interest in the proceedings.
- A description of what issues the applicant proposes to address and how he or she proposes to address them.
- A discussion of the applicant's expertise and experience related to the proceeding.
- A discussion of how the applicant meets the Comptroller General's eligibility criteria.

- o An estimate of the amount of funding required and what percentage is being requested from FDA.
- o A list of all Federal administrative proceedings involving a hearing on the record in which the applicant has participated, including the ideas expressed and any amount received from the Federal government in connection with the participation.

This information was to be reviewed and a recommendation made by the presiding officer of the proceeding. The recommendation was to be submitted to the Evaluation Board along with all documentation. All communications between the presiding officer or the Board and the applicant were to be in writing and made part of the official transcript of the proceeding.

The Evaluation Board was to submit a written response to each application. The response was to include a statement as to why the Agency reached the conclusion it did. If approved, the applicant could be reimbursed for salary costs of the applicant and/or his employees, as well as any technical or legal fees; transportation and other travel related costs; research/demonstration costs; and other necessary costs. Additional funding in excess of the initial award could be made if the Board or presiding officer requested the applicant to perform additional work or if the applicant demonstrated that the presentation had been subject to an unforeseeable and material change.

THE FOOD AND DRUG ADMINISTRATION'S (FDA) ADVISORY COMMITTEE PROGRAM

Community Nutrition Institute. Building Consumer Capabilities Within FDA Advisory Committees: Manual. Washington, D.C.: Community Nutrition Institute, 1980.

Food and Drug Administration. Public Hearing Before a Public Advisory Committee. 21 USC 1.14.

_____. FDA Public Participation Program. (Draft Response to Executive Order 12160).

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The FDA has an extensive program to involve consumers in its advisory committees. FDA has also recently established a new system to select consumers for its committees. This system has been fully operational since Spring 1980. A Consumer Consortium as well as a Participant Clearinghouse have been established, and FDA has also contracted with the Community Nutrition Institute to provide training to consumer representatives. Consumers, interested in participating on an FDA advisory committee, submit applications to the Participant Clearinghouse. These applications are reviewed by the Consumer Consortium, a group consisting of nine elected representatives from various consumer organizations which meet certain organizational criteria including a minimum membership of 30 and an organizational publication. Selection criteria for consumer representatives on advisory committees include:

- o Communication skills
- o Established link and accountability to consumer/community-based organizations
- o Ability to make decisions
- o Leadership ability
- o Analytical skills
- o Interpersonal skills
- o Ability to follow through
- o Technical understanding and experience

In addition, the Consortium takes into account ethnicity, income, geography, sex, age, and religion in its considerations to assure that as many different consumer subpopulations as possible are represented.

After reviewing the applications, Consortium members interview the best qualified applicants by telephone. The Consortium then will recommend approximately two names to the Executive Secretary or Panel Administrator of the advisory committee/panel concerned. The Secretary/Administrator makes the final selection.

Selected participants are considered special government employees and are reimbursed for their travel expenses. In addition, they are paid $128.80 per day for attendance at meetings. In some cases, consumers are also paid for the time required to prepare for meetings. They are not reimbursed, however, for any expenses related to the procurement of any technical or legal services. They are provided with access to FDA technical expertise by filing requests for information under the Freedom of Information Act with the Executive Secretary/Panel Administrator. This procedure is a legal precaution undertaken because of the potential involvement of proprietary data submitted by pharmaceutical companies. This access is in addition to the background information which is provided to all committee members.

THE NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION'S (NHTSA) FINANCIAL COMPENSATION PROGRAM

National Highway Traffic Safety Administration: Department of Transportation's Demonstration Program to Provide Financial Assistance to Participants in Administrative Proceedings, Washington, D.C.: August 1977.

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The NHTSA's program for funding consumer participation was cut from their FY 1980 budget. The program had been a 1-year demonstration project which had a line item budget of $125,000. During its operation, the program funded over 100 participants which had been selected by an independent Evaluation Board composed of representatives from the Department of Transportation's Consumer Affairs Office, an NHTSA official, and a representative from the Chief Counsel's Office. Potential participants were notified of the existence of the program through Federal Register announcements and a mailing to potentially interested members of the public. Small business representatives

were eligible for reimbursement, but were not funded during the 1979 program's operation.

NHTSA conducted an evaluation of an early pilot program in 1977. In their report, they noted:

> "By ensuring that more informed and interested citizens can actually afford to develop and present their views and interests, instead of merely notifying them of the opportunity to participate if they can afford that cost, the Department has created the conditions that provide greater assurance of fair, responsible, governmental action... The Department will (also) be able to develop regulations that are more secure from judical and legislative attack since such regulations will be based on a more complete assessment of the competing arguments and interests."

Included in the recommendations for improving the program were the following:

- "Participants should be compensated at the prevailing market value for their services, except that compensation will be limited to amounts paid to comparable DoT employees...
- To decide which proceedings should be funded the decisionmaking authority would evaluate their (1) contribution to fulfilling agency goals; (2) costliness to consumers or manufacturers; (3) benefit to the public; (4) controversiality from the viewpoint of consumers or manufacturers; (5) the availability of funds; (6) the time available to complete them...
- (T)he regulations should indicate that the applicant must overcome a strong presumption against the negotiation of awards to be eligible for additional funds, and that the Department has no obligation to renegotiate such awards...
- An individual should be presumed to have demonstrated financial need if his income is less than $30,000."

THE SMALL BUSINESS ADMINISTRATION'S (SBA) FINANCIAL COMPENSATION PROGRAM

Small Business Administration. Proposed Consumer Affairs Program. Federal Register, Vol. 45, No. 26, Wednesday, February 6, 1980, pp. 8236-8238.

_____. Part 101-Administration. 13 CFR Part 101.

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The Small Business Administration (SBA) does not have a financial compensation program for public participants. They have noted:

> "Perhaps as a result of the negligible effect which SBA programs and activities have on the consumer, SBA has not had extensive consumer participation or other important indication of consumer interest in the development and review of its rules, policies and programs."

C. Non-Agency Specific Information Related to Financial Compensation Programs

Administrative Conference of the United States (ACUS). Recommendation 68-5: Representation of the Poor in Agency Rulemaking of Direct Consequence to Them. 1 CFR 305.68-5.

This ACUS Recommendation states:

"When necessary to assure adequate representation for the poor, agencies should pay the personal expenses and losses incurred by individuals incident to their participation in rulemaking hearings. Congress should support agency requests for funds and for authority, where none exists, to make discretionary payments for this purpose.

_____. Recommendation 71-6: Public Participation in Administrative Hearings. 1 CFR 305.71-6.

This ACUS recommendation states the following factors should be considered in selecting participants:

"(a) The nature of the contested issues;
(b) The prospective intervener's precise interest in the subject matter or possible outcome of the proceeding;
(c) The adequacy of representation provided by the existing parties to the proceeding, including whether these other parties will represent the prospective intervener's interest and present its views, and the availability of other means...to protect its interest;
(d) The ability of the prospective intervener to present relevant evidence and argument; and
(e) The effect of intervention on the agency's implementation of its statutory mandate."

This recommendation also touches on other topics which might relate to a financial compensation program such as making pertinent documents available.

Comptroller General of the United States. "Letter to Miles W. Kirkpatrick, Chairman, Federal Trade Commission." File B-139703, July 24, 1972.

In this ruling, the Comptroller General noted:

"The appropriations for the Commission (FTC) are normally available for 'necessary expenses.'...(A)ppropriations are enacted in the form of lump sums with no specific limitations as to use. Thus, the determination of what constitutes 'necessary expenses' is left to the reasonable discretion of the Commission.

...(T)he Commission is authorized to determine the administrative necessity for full preparation of cases before it in connection with the

proper execution of its functions. It follows that the use of Commission appropriations to assure such full preparation of cases by impecunious litigants would constitute a proper exercise of administrative discretion regarding the expenditure of appropriated funds."

Comptroller General. "In re Costs of Intervention - Nuclear Regulatory Commission." File B-922888, February 19, 1976.

In this ruling, the Comptroller General noted that the Nuclear Regulatory Commission:

"has the statutory authority to facilitate public participation in its proceedings by using its own funds to reimburse intervenors when (1) it believes that such participation is required by statute or necessary to represent adequately opposing points of view on a matter, and (2) when it finds that the intervenor is indigent or otherwise unable to bear the financial costs of participation in the proceedings."

This ruling was more applicable to other agencies than the 1972 rulings cited above; liberalized the intervenor requirement to include intervenors who are "otherwise unable to bear the financial costs;" and authorized the payment of attorneys' fees.

It did, however, state that:

"it would be advisable for such parameters of such financial assistance, and the scope and limitations on the use of appropriated funds for this purpose to be fully set forth by the Congress in legislation, as was done in the case of the FTC by the 'Magnuson-Moss' Act."

Comptroller General. "Letter to Congressman John E. Moss, Chairman, Oversight and Investigations Subcommittee, Committee on Interstate and Foreign Commerce." File B-180224, May 10, 1976.

In this ruling, the Comptroller General extended the NRC ruling to nine other regulatory agencies and stated:

"(I)t is within the discretion of each individual agency to determine whether the participation of the particular party involved is necessary in order for it to properly carry out its functions and whether the party is indigent or otherwise unable to finance its participation."

Comptroller General. "Letter to Congresswoman Yvonne Brathwaite Burke." File B-139703, September 22, 1976.

In this ruling, the Comptroller General reaffirmed the Commission's authority to reimburse certain expenses incurred by participants in FCC proceedings. He also stressed:

"...the prerequisite to such payments is a determination by the agency that the payments are 'necessary' to the accomplishment of its functions. Certainly this would include obtaining presentations or other forms of participation which enable the full and fair resolution of matters before the Commission. However, we would emphasize that our decisions are limited to situations in which the payment, as well as the participation is necessary: that is, lack of financial resources on the part of the person involved would preclude participation without reimbursement. Accordingly, the Commission must determine that both the participation itself and payment therefor are necessary."

Comptroller General. "In re Costs of Intervention - Food and Drug Administration." File B-139703, December 13, 1976.

This decision clarified the Comptroller General's previous rulings. He noted:

"(I)t would be sufficient if any agency determines that a particular expenditure for participation 'can reasonably be expected to contribute substantially to a full and fair determination of' the issues before it, even though the expenditure may not be 'essential' in the sense that issues cannot be decided at all without such participation."

Consumer Affairs Council. "Draft Consumer Programs." Federal Register, Vol. 44, No. 238, Monday, December 10, 1979, pp. 71101-71398.

The publication contains new or revised Federal consumer programs developed in response to Executive Order (E.O.) 12160. It includes a full copy of E.O. 12160, a Consumer Response Form for Executive Order 12160, and an Executive Order 12160 Compliance Checklist. It discusses these documents, their impact on consumers, and what Federal agencies have done since E.O. 12160 was signed.

Cramton, Roger C. "The Why, Where and How of Broadened Public Participation in the Administrative Process." The Georgetown Law Journal, Vol. 60, No. 3, February 1972, pp. 525-550.

This article arises from a study undertaken by the Administrative Conference of the United States. One of the major points of the article is that effective consumer participation is not likely to be possible without some type of financial support. Without such participation, consumer issues are not likely to be addressed because agency staff tend to base decisions on the information that is available or presented to them.

General Services Administration. Federal Advisory Committees: Eighth Annual Report of the President. Washington, D.C.: General Services Administration, March 1980.

This publication lists advisory committee statistics for FY 1979. It also includes copies of: the Federal Advisory Committee Act (Public Law 92-463); Executive Order 12024, which relates to the transfer of certain advisory committee functions to GSA; OMB Circular A-63 with transmittal memoranda from OMB, which sets policy and procedures for advisory committees; and the GSA Federal Property Management Regulations.

"Intervenor Funding: Public Participation in Rulemaking." At Home with Consumers. Vol. 1, No. 3, January 1980, pp. 1-8.

This issue contains interviews with Senators Edward M. Kennedy and Allan K. Simpson who expressed opposing points of view towards the desirability of funding public participation in agency decision making.

Senator Kennedy pointed to the growing costs of Federal regulations and success stories from such compensation/ participation programs as evidence of the need for them. He also noted:

"One Congressional study found that regulated interests generally outspend consumers and small business (for participation costs) by a wide margin, sometimes as much as 50 to 1. Even in proceedings with public participation funding, consumer groups are outspent 3 to 1."

Senator Simpson, on the other hand, notes:

"I am opposed to this kind of program because I feel it is incompatible, in a free society, for the government to be financing any group of lobbyists, no matter how well intentioned it might be. If a group claiming to speak in the public interest truly does, then it would be able to raise money from the public to finance its activities, including those to appear before federal regulatory agencies."

He also noted:

"Therefore, I introduced a series of amendments to FTC's 1980 and 1981 authorization bills that would either restrict, or, hopefully, terminate this (intervenor funding) program entirely. I plan to offer similar amendments to several other regulatory reform bills..."

Maryland Citizen's Consumer Foundation and the Consumer Council of Maryland. Effective Consumer Representation. U.S. Office of Consumers' Education, Department of Health, Education, and Welfare, 1979.

This three volume series describes a model training program for consumer members on licensing and regulatory boards and commissions. It has applicability to the training of consumers for participation on other types of government boards and advisory committees.

The report notes advantages and disadvantages of consumer participation.

"Some advantages are, public members:

1. Reduce the potential for board decisions which favor industry over the public.
2. Reduce the potential for decisions which illegitimately favor one faction of an industry over another.
3. Institutionalize public participation in government decision making.
4. Decrease public suspicion and thereby augment public confidence and trust in government.
5. Expand the range of skills, talent, training, and perspectives available for higher quality and more creative board action.
6. Can raise the level of board discussion to include re-examination of the unscrutinized "givens" in any industry or profession.
7. Reduce the barriers for "the average citizen" to address the board.
8. Lend credibility to board decisions and legislative advocacy.

Some disadvantages are, public members:

1. Impede board activity if technical issues are not understood by lay members.
2. Imply that policy-making has been misguided in the past; could antagonize professional or industry members.
3. May cause split vote. Board conflicts may reduce the board's credibility in the eyes of licensees. This could reduce adherence to the occupational regulations.
4. May not know the informal mores of a business or profession and thus prevent the choice of the most effective punishment of an offender or attack on a problem.
5. Lack economic self-interest and may lose enthusiasm for board participation and allow domination by industry members.
6. May overregulate the profession in an attempt to improve quality."

It also defines "consumer member" as someone who:

"represents the interests of those who are actual or possible purchasers, leasees, or recipients of consumer goods, consumer services, consumer realty, or consumer credit"

Office of Consumer Affairs (OCA). Consumer Action Update. Washington, D.C.: Office of Consumer Affairs.

This is a bulletin that is published twice a month by OCA to inform consumers of current and pending legislation and regulations and related areas of interest. It has a circulation of about 7,000.

Office of the President of the United States. Executive Order 12160: Providing for Enhancement and Coordination of Federal Consumer Programs.

This Executive Order establishes the office and functions of the Consumer Affairs Council; outlines consumer program reforms, including a separate

consumer affairs program budget, civil service reforms for consumer affairs staff, and other administrative provisions.

Reich, Robert G. "Toward a New Consumer Protection." University of Pennsylvania Law Review. Vol. 128, No. 1, November 1979, pp. 1-39.

Mr. Reich, Director of Policy Planning in the Federal Trade Commission, begins his article with:

"Consumer protection is everywhere in retreat."

He explains that unfavorable economic conditions as well as a "growing public unease about the function of consumer protection" are two major contributing factors. His premise is:

The least costly and most effective strategy for consumer protection is to increase the stake which sellers have in building and maintaining goodwill...Substitution of the choices of bureaucrats for those of consumers carries with it a not so subtle implication that consumers are relatively powerless, if not incompetent, when faced by the combined force of corporate greed and Madison Avenue hype...The goal of consumer protection should be to minimize the likelihood that consumers will misestimate product risks and hidden costs, by placing the responsibility for avoiding such misestimations on sellers and manufacturers when they are better able to do so than consumers.

Richardson, Lee. "Accountability--Looking from the Inside Out." American Council on Consumer Interests: Proceedings of the 24th Annual Conference, April 19-22, 1978, pp. 211-216.

This article discusses ways in which consumer advocates have influenced Federal regulatory and administrative proceedings and recommends that consumer organizations target research towards regulatory issues so as to provide consumers with data needed to represent consumer interests more effectively. The author had been the Director of the Office of Consumer Affairs of the Department of Health, Education, and Welfare.

Ryan, Mary Kay. "Accountability: ACCI at a Crossroad." American Council on Consumer Interests: Proceedings of the 24th Annual Conference, April 19-22, 1978, pp. 11-15.

The author surveyed the present and future roles of consumer education. She stated the belief that many failures of consumer initiatives are due to inadequate underlying research. She concluded that:

"If ACCI is indeed at a crossroad now--along with the rest of the consumer movement--should we not consider undertaking the following:

1. Identify five to ten major issues that are on the horizon where research needs to be conducted from a consumer standpoint. Develop a plan for acting as a catalyst to insure that research is begun in the priority areas.
2. Canvas government and private programs to identify users of consumer research; compile a list of their research and data needs; make this available to our membership.
3. Expand our clearinghouse service to include a tracking system for logging research starts. This service should encourage cross-checking and expanded research cooperation among our members."

The existence of such a research base might facilitate consumer representation in many standards developing activities and/or agency regulatory proceedings.

U.S. Senate. "A Participation Expenses Act of 1980." 96th Congress, 2nd Session, Committee Print, February 29, 1980.

This Senate bill on intervenor funding would authorize any Federal agency to recommend to the Administrative Conference of the United States (ACUS) that certain members of the public be awarded financial assistance to participate in rulemaking, licensing, ratemaking, or adjudication. The ACUS would be authorized to award financial assistance to cover the costs of participation based on agency recommendations.

Provisions of the bill include a requirement for information on:

1. The number of times an applicant has received funds for participation;

2. How much of the applicant's operating costs is taxpayer's money and a general description of the applicant's other sources of funding.

The bill also intends that a portion of the funds be used to fund small business and that no one applicant receive more than $100,000 or 20 percent (whichever is greater) of such funds awarded in proceedings of an agency in a fiscal year.

United States Court of Appeals for the Second Circuit. "Green County Planning Board v. Federal Power Commission (FPC)." 554F 2d 1227, (2d Cir. 1977) (en banc), cert. denied, 434 U.S. 903 (1978).

The Court rejected the Comptroller General's ruling that the FPC's statutory authority to expend appropriations for "expenses necessary for the work of the Commission" is sufficient to authorize reimbursement of participants in FPC proceedings.

The Federal Energy Regulatory Commission succeeded FPC as party to the litigation. FERC reversed FPC's earlier position that it lacked authority under its organic statute and asked the Supreme Court to remand the case to the Court of Appeals for reconsideration. The Supreme Court denied the petition without taking a position on the merits of the case.

Attorney General Griffin B. Bell. "Letter to Senator Strom Thurmond, June 14, 1978.

This letter confirmed an earlier Justice Department decision that the Greene County case should be narrowly construed as having no applicability to any agency other than the Federal Power Commission or its successor.

United States District Court for the District of Columbia. "The Chamber of Commerce of the U.S. v. U.S. Department of Agriculture." 459 F. Supp. 216, 221 (D.D.C. October 10, 1978).

In this case, Judge Flannery noted:

"numerous authorities support the conclusion that agencies in general, and the USDA in particular, have the implied power voluntarily to fund the views of parties whose petition might otherwise go unrepresented."

The Chamber of Commerce had sought to enjoin USDA from funding a study by a consumer organization concerning the possible impact on consumers of a proposed rule. The injunction was denied.

United States Regulatory Council. Calendar of Federal Regulations: Appendix 1: Public Participation in the Federal Regulatory Process. Federal Register, Vol. 44, No. 230, Wednesday, November 28, 1979, pp. 68384-68399.

This Appendix briefly describes the consumer participation programs of each Federal agency as well as the general requirements for public participation in the Executive and Independent Agencies of the Federal Government including: the Administrative Procedures Act, Executive Orders 12044 and 12160, the Freedom of Information Act, the Federal Advisory Committee Act, and the Sunshine Act.

This Appendix also defines "consumer" as "any individual who uses, buys or acquires real or personal property, goods, services or credit for personal (,) family or household purposes." It defines "public" as "any member of the U.S. populace including business and industry and other regulated sectors."

U.S. Senate Committee on Governmental Affairs. Study on Federal Regulation: Volune III - Public Participation in Regulatory Agency Proceedings. S. Doc. No. 95-17, 95th Congress, 1st Sess., July 1977.

This study recommended that Congress:

"enact legislation authorizing agencies to provide compensation to eligible persons for costs incurred in participating in agency rulemaking, licensing and certain other proceedings....Until such time as general legislation for compensation of public participation costs is enacted, regulatory agencies should implement their own programs to compensate eligible participants in agency proceedings as appropriate."

Major findings of the study included:

"At agency after agency, participation by the regulated industry predominates -- often overwhelmingly. Organized public interest representation accounts for a very small percentage of participation before Federal regulatory agencies. In more than half of the formal proceedings, there appears to be no such participation whatsoever, and virtually none at informal agency proceedings. In those proceedings where participation by public groups does take place, typically it is a small fraction of the participation by the regulated industry. One-tenth is not uncommon; sometimes it is even less than that. This pattern prevails in both rulemaking proceedings and adjudicatory proceedings, with an even greater imbalance occuring in adjudications than in rulemaking.

The single greatest obstacle to active public participation in regulatory proceedings is the lack of financial resources by potential participants to meet the great costs of formal participation. Lack of funds has prevented public participation in many important proceedings.

The regulated industry consistently outspends public participants by a wide margin in regulatory agency proceedings. In every case or agency reviewed, industry spent many times more on regulatory participation than their public interest counterparts. In some instances, industry committed as much as 50 to 100 times the resources budgeted by the public interest participants. For example, in 1976 the nation's 11 trunk airlines spent more that $2.8 million on outside counsel to represent them in regulatory proceedings before the CAB. By contrast, the Aviation Consumer Action Group, the principal representative for public interest organizations at CAB proceedings, has a total 1976 budget of $40,000, of which approximately half was spent on participation in CAB proceedings.

Lack of resources has limited the amount of technical expertise that participant groups have been able to bring to bear in agency proceedings.

Opportunities for citizen participation are hampered by significant administrative costs such as transcript fees and reproduction of required materials."

IV. CONSUMER INTEREST REPRESENTATION--THE STANDARDS DEVELOPING ORGANIZATION PERSPECTIVE

A. Overview

Major standards developing organizations in the United States have long recognized the necessity of involving product users in their standards writing activities. For many decades industrial and institutional users of products predominated in these activities since relatively few standards were written for household/personal use type products. Consumers were frequently uninvolved and uninterested because they were both unorganized and largely unaware of how standardization affected the goods and services available in the marketplace.

In 1923, the President of The American Society for Testing and Materials (ASTM) at that organization's annual meeting emphasized: "the importance of maintaining an adequate representation of consumer interests at committee meetings to secure a real balance of producers and consumers in the formulation of standards and specifications." In her use of this same reference, Winfree stated: "It is clear in this statement that ASTM had begun to direct its attention to the ultimate consumer*. If not directly involving that consumer, at least the society was expressing the concern that his or her needs be represented in ASTM standards development." ASTM staff interviewed for this project consistently repeated and supported their organization's commitment to committee balance.

However, in addition to this commitment to committee balance is a certain wariness. While there is a "consumer interest" category just as there is a "producer interest" category, it is far easier to get technically qualified producer volunteers to serve on standards developing committees. In the aggregate, consumers and producers may have equal interests in the impacts of standards. Yet, individual consumers are likely to have a far smaller interest than any individual producer representative. Even the aggregated interests of all the individual members of a consumer organization are likely to be smaller than the interest of any individual producer representative. This lesser incentive makes recruitment of consumer representatives very difficult in most instances.

Relatedly, there may frequently be no consensus consumer interest just as there is not always a consensus producer interest. While individual committee members are identified by interest, their personal experiences may be their most significant contributions to the development of any particular standard. Consequently, ASTM does not feel that rigid quotas for the representation of any interest are desirable. ASTM believes that its current requirement preventing any interest from attaining the majority of any committee's membership is adequate to protect all interests.

As the 1980 ASTM President noted regarding consumers: "The problem is how to find these people, how to assemble them, and how to get them to coordinate

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*See Winfree in Section B, Annotated Bibliography.

their thoughts and speak with a voice representive of their particular interest." (See first entry in Section B.)

There is indeed a problem, in part because there may have to be tradeoffs among ASTM principles--especially the commitment to committee balance versus the commitment to technical committee independence. ASTM has long taken great pride in its system which essentially provides the climate in which technical experts can set their own priorities and reach their own technical consensus. For instance, an ASTM promotional brochure asks the question "What is ASTM?" and proceeds by answering (emphasis added) that:

> ASTM is a management system for the development of voluntary full consensus standards. It provides a legal, administrative, and publication forum within which producers, consumers, and those representing the general interest (hereafter called GI's) can meet on a common ground to write standards which will best meet the needs of all concerned.
>
> ASTM headquarters has no technical research or testing facilities. Such work is done voluntarily by those who work within the ASTM system--technically qualified members of the Society located throughout the world.

Too much attention to recruiting, training, and, especially, to funding consumer representatives could be seen by other participants as interfering with the voluntary nature of the process. The impacts of this perception would be especially important to consider in evaluating the activities of standards developers such as the National Committee for Clinical Laboratory Standards (NCCLS). Usually, NCCLS does not even consider patients to be users of the products for which it writes standards. NCCLS contends that its costs would become "unbearable" if members of the general public had to be subsidized to serve on its committees. (See Kreitges.)

Regarding standards developer subsidization of consumer representation, two considerations arise. First, standards developing groups get most of their operating funds from the sale of their printed standards. For example, overall publication sales account for about three-quarters of ASTM revenues. Standards, as technical documents, have virtually no sales to either individual consumers or consumer groups. Increased consumer representation could well increase the costs of producing standards, but is highly unlikely to create any increase in publication sales and revenues. Second, the system is now essentially a voluntary, technical process. Most advocates of increased consumer participation defend the increase not on the primary grounds of adding a new and different technical input, but rather on socio-economic grounds. Such a shift of emphasis would effectively alter the very nature of the system at a cost to those who have been its longest term supporters and contributors.

An Underwriters Laboratories Vice President noted that in a UL committee working under the CPSC offeror process there were no substantial differences between consumers and non-consumers in their voting habits on technical and other matters. (See Hoffman.) Consequently, the article implied that consumer representation did not provide clear benefits; especially since the committee dealt with a household item--television sets--where consumers ought to have been able to make their greatest impact. In contrast, the General Counsel

of NCL argued that the greatest consumer contributions came in the deliberations before such voting took place. The areas in the standardization process where standards developers and consumers look for indications of benefits (e.g., voting, writing of drafts, and determination of standards scope) can lead to very different evaluations of any proposed change in operations.

In philosophical terms, the committee system for voluntary standards development might be seen as a descendant of Adam Smith's "Invisible Hand of the Marketplace". Its supporters claim that it is a self-correcting mechanism that works best without outside interference--especially government interference. As an indicator of this self-correcting nature, standards developers noted that a number of publications are designed to both help committees better understand consumer concerns and needs and to assist consumers in understanding the process of standardization. The four ANSI publications noted in Section B are examples of this effort.

Some individuals contacted in our research did not agree that current consumer participation levels were too low. One NBS staff member serving on a standards developing committee commented that: "The consumer interest really is represented in our work. Our biggest problem is that the representation isn't highly visible to the casual observer. I'm not being facetious, but just changing how we label our members -- calling more of them public interest members, for instance -- might solve a lot of our image problem." The Dixon book, annotated in Section B, which was produced as a report to the National Fire Protection Association (NFPA), contains a very articulate discussion of "interest representation and procedural fairness" in voluntary standards development. Dixon concludes, and NFPA agrees, that as long as there is informed consumer input achieved through procedural fairness, there is no need for precise representation quotas and controls.

Although somewhat dated, the Peyton speech, cited in the Bibliography, shows another important variation in the standards developer's attitude toward consumer concerns. Despite effectively noting that more participation would be useful and desirable, it argues that the central problem is education. Neither consumers nor those in government claiming to be acting for consumers adequately understand either the standardization process or its benefits. Thus, many ANSI consumer programs are concerned relatively more with educating the consumer (and the government) rather than directly involving more consumers in standards development. Similarly, one of Winfree's recommendations for ASTM was that: "A media campaign should be launched to publicize these (consumer) recruitment efforts..." One standards developing organization staff member stated that since technical considerations were of paramount concern in writing standards that it was far easier to teach technical people about consumer attitudes and needs than it was to teach consumers about technical processes.

For most categories of technical participants in voluntary standards development, membership recruitment is not a very costly undertaking. Most major professional associations either write standards themselves and/or have had ongoing ties to major standards developing organizations. Professional journals routinely carry information about standards under development related to that profession. For engineers (among other professions), standardization

work accrues professional prestige and recognition. In decided contrast to this situation is the multifaceted problem of consumer recruitment.

If an individual is employed by a firm whose products would be affected by standards, standards organizations have not classified that individual as a consumer even though he or she may indeed purchase the products in question for personal use and even though the individual may have demonstrable credentials as a consumerist. This "conflict of interest" determination may effectively eliminate most technically qualified consumer members from many committees writing standards. Not only does this severely restrict the number of possible consumer recruits, it eliminates those potential consumer representatives who would be most susceptible to traditional recruitment methods. Traditional membership recruitment has centered around personal contacts by existing committee members and publicity through trade and professional journal articles. Neither of these has been adequately productive for increasing consumer membership.

In June 1980, a very positive sign of the continuing standards developing organization commitment to consumer representation appeared. The ANSI Consumer Council published a Policy Statement on "Consumer Participation in Standardization Work." Reproduced in full in the following annotations, it began:

> "There should be provision within the system for consumer participation in the initiation and planning of the programs of standards work, both national and international, as well as in policy matters relevant to the consumer interest."

B. Annotated Bibliography

_____. "An Interview with ASTM President Wayne Ellis". ASTM Standardization News, January 1980, pp. 8-15.

This interview with ASTM's president for 1980 provides a useful insight into policy level views on consumer involvement in voluntary standards development. Mr. Ellis stated that: "In ASTM standards committees we want consumer participation to be broadly representative of consumers interested in each particular standards area. The problem is how to find these people, how to assemble then, and how to get them to coordinate their thoughts and speak with a voice representative of their particular interest."

When asked whether consumers on ASTM committees should represent a particular group or represent themselves as individuals, Mr. Ellis answered: "I think consumer participation should follow the pattern of other interest groups in ASTM, whereby an interest group is identified but participation is by individuals. A group spokesman, while expounding a position of the group, involuntarily interjects individual experience into it, which is a useful feature of the system. Interest groups can't always arrive at a consensus. It seems to be that group participation is not the answer, although for an interim period it may be the best available."

Mr. Ellis sees the field of medical standards as a growth area for the 1980's, but is concerned about finding enough medical experts who have time to devote to standardization work. He notes that "...standards in this field have been traditionally slow in coming."

American National Standards Institute. ANSI and the Consumer. New York, New York: American National Standards Institute, October 1976.

A promotional brochure designed to tell in basic terms how and why consumers and ANSI have common interests. Its most important feature is the address and telephone number of whom to contact for further information about ANSI's role in consumer activities within the voluntary standards developing system.

American National Standards Institute. Guide for Consumer Product Standards: ANSI Consumer Council Publication 1. New York, New York: American National Standards Institute, June 1972.

This guide was prepared by the American National Standards Institute's Consumer Council. It is intended to assist in preparing consumer product standards by providing for (1) systematic consideration of all factors likely to be essential in satisfying consumers' reasonable expectations, and (2) selection of characteristics that to some degree can be agreed upon or treated uniformly, and are therefore appropriate subjects for standardization. A consumer, as defined in the ANSI Bylaws, is "a person who uses goods and services to satisfy his personal needs and desires rather than to resell them or to produce other goods or services with them." A consumer product is defined as an article customarily produced or distributed for purchase by a consumer.

Although it covers a wide variety of issues, the Guide's Foreword cautions that:

> "It should be emphasized that a particular standard need not include each subject listed in this guide. The decision to include or exclude any subject is to made by standards preparation groups, based on their experience with, and knowledge of, each product."
>
> "Also, not every aspect of every consumer product can be found in this checklist. Again, utmost care should be exercised to include all pertinent points that characterize the product under consideration, so that the standard satisfies the needs and expectations of the consumer, and, at the same time, does not limit his choice unnecessarily."

The Guide's checklist could form the outline for an evaluation by a Federal agency of a consumer product standard produced by a voluntary standards developer. Relatedly, the checklist could form the outline for an evaluation of a standard by consumer organizations or individual consumers regardless of whether they were represented on that standards developing committee.

American National Standards Institute. Guidelines for Organizing a Product Safety Program: ANSI Consumer Council Publication 2 (Revised). New York, New York: American National Standards Institute, November 1978.

According to the publication's Introduction:

"Manufacturers have a responsibility to produce products that satisfy the safety expectations of society. These expectations have recently accelerated, with the result that safety must receive more emphasis than ever before in decisions concerning the design, production, and marketing of products, and including ultimate intended and foreseeable uses."

"Therefore, product safety activities need to be integrated into certain specific management procedures and specific functions of an organization. General guidelines and a detailed checklist are presented in this publication to aid the manufacturer in developing the activities and procedures needed for this particular organization. There is no intent that indicated functions or activities need be carried out by a specialist staff. In some firms several or all of the staff activities can be the responsibility of one person -- possibly on a part-time basis. Also, it should not be interpreted that responsibility for the safety of a product should be separated from the product executive."

"The guidelines and checklist are designed to aid in consideration of the product safety elements that may be needed in specific situations. It is not intended that each factor be a part of every program; nor should these factors be considered complete for any or every situation. For these reasons the guidelines are not intended for direct adoption as either voluntary or mandatory standards."

The publication's guidelines and checklist should be useful background reading for consumer members on voluntary standards developing committees; they show the range of possible safety and safety-related product aspects which consumers could consider.

American National Standards Institute. Guidelines for Standards Briefing Seminars/Consumer Sounding Boards Programs: ANSI Consumer Council Publication 3. New York, New York: American National Standards Institute, June 1975.

Initiation of a consumer information project was undertaken cooperatively in 1972 by five organizations concerned with the development of voluntary standards, their coordination, and their effective use. The five groups are the American National Standards Institute (ANSI), the American Society for Testing and Materials (ASTM), the National Bureau of Standards of the U.S. Department of Commerce (NBS), the National Fire Protection Association (NFPA), and Underwriters Laboratories (UL). Each group contributed funds to get the project underway.

Early in the planning stage there was agreement that "Standards Briefing Seminars for Consumers" were needed to begin the project and that these should be held in several regional areas to develop a format for future briefings.

In 1973 three regional briefings were held, steered by a Working Group of the Consumer Education and Public Relations Committee of the ANSI Consumer Council. Representatives of all five cooperating sponsors were members of the working group. Seminars were held in the Washington, D.C. area (Gaithersburg, Maryland) with NBS as host, in the Chicago area (Northbrook, Illinois) with UL the host, and in New York City with ANSI the host.

From these exploratory meetings a pattern for future action was established. It soon became obvious that a three-step program was needed:

1. First, the initial Standards Briefing Seminar to provide general information on what standards are, what they do, how they are developed, and who the groups are that develop voluntary consensus standards.
2. Second, the organization of a "Consumer Sounding Board" to provide technical committees working to develop consumer product performance or safety standards a means of conferring with a cross section of ultimate consumers. The Consumer Sounding Board is not intended to develop technical expertise but rather to provide a dependable report of broad consumer experience, attitude, and opinion regarding the product involved for the use of standards development committees.
3. Third, the "Intensive Briefing Session Group," by which volunteers from a Consumer Sounding Board may be given special informational briefings on how a consumer may become a contributing member of a technical committee which is working on a voluntary product performance or safety standard.

This publication represents an attempt to provide guidelines to meet these three identified needs. These guidelines provide a useful reference to any voluntary standards group seeking to expand its consumer input.

American National Standards Institute, Consumer Council. Policy Statement: Consumer Participation in Standardization Work. New York, New York: American National Standards Institute, June 1980.

The following policy adopted by the Consumer Council is addressed to the groups which cooperate within the voluntary standards system coordinated by ANSI.

> "For the purposes of this statement, (1) a consumer is defined as an individual ultimate user of the products or services for which standards are being developed who is not currently engaged in the manufacture or distribution of same or involved with government regulations related to same; (2) the system refers to the ANSI coordinated federated standards system; and (3) the member body refers to any participating group within the ANSI coordinated federated standards system.
>
> "1. There should be provision within the system for consumer participation in the initiation and planning of the programs of standards work, both national and international, as well as in policy matters relevant to the consumer interest.

"2. Within the system, it shall be the obligation of all technical committees executing standards projects affecting the interests of the general public to invite consumer participation.

"Where consumer resources are limited, an alternative system of consumer representation is set out in the annex as offering a minimum requirement.

"3. Where a technical committee is developing an International Standard primarily of interest to consumers, member bodies should obtain the active participation of consumers in national delegations.

"It is essential that they are involved when the delegation is briefed and that the consumer view is taken into account when decisions on the national position are taken.

"4. Standards work by nature can be technical and complex. Where technically competent consumers are not available, member bodies should provide consumer representatives with guidance (e.g., through a designated reference person) on standards procedures and briefing on technical issues in order to make their contribution both effective and based on a knowledge of real possibilities.
"5. Member bodies should ensure effective communication to the general public of the results of their standards work of interest to consumers, making use, whenever possible, of publicity expertise to encourage application of standards and feedback.

"6. Where the representation of consumers is hampered through lack of finance, member bodies should use their best efforts in finding solutions to overcome these difficulties.

"7. Member bodies should be encouraged to examine measures to 'sound' consumer opinion through existing consumer orgnizations or, if no such organizations exist, on their own initiative.

"8. Member bodies are invited to study the composition and terms of reference of the various consumer committees of other member bodies and to consider whether any changes in their own structures would be appropriate in order to comply with these recommendations.

"9. Particular attention should be paid to a close coordination of all activities arising from these recommendations within this country. This would also facilitate a common approach to matters of consumer interest in international standardization."

American Society for Testing and Materials. Guide to ASTM Consumer Standards Philadelphia, PA, February 1968.

The standards in this Guide are intended for use by organizations and individuals concerned with programs of consumer protection and education. Most of these standards require some technical proficiency for their proper use, thus they are not generally useful to the ultimate consumer in making his or her purchase.

Dixon, Robert G. Jr. Standards Development in the Private Sector: Thoughts on Interest Representation and Procedural Fairness. Boston, Massachusetts: National Fire Protection Association, 1978.

In response to substantial Federal sector activity concerning the "private standards writing industry", the National Fire Protection Association asked the author "to see if it would be possible to develop a model for representation of interests on the technical committees which constitute the core of the process of developing consensus on various types of voluntary safety and product standards in the private sector." This volume was prepared in response to that request.

Dixon begins by noting: "The private standards bodies operate, in effect, a system of private rulemaking with many of the attributes and problems of governmental policy-making. The contributions of the private standards system to the needs of a product-ridden, safety-conscious society are considerable, and are appreciated even by proponents of some modification or regulation." After discussing "sources of concern about private standards-making", the author analyzes representation theory based upon his survey of the available literature. He covers such items as: agency and the proxy model of representation; governmental-legislative models of representation; and proportional representation systems. In his chapter on representation realities in private standards bodies, Dixon differentiates between representable interests and strata of society. There he stated: "Despite the assertions of the critics of the private standards system about underrepresentation of "consumers", it is difficult if not impossible to find a principled formula for according direct representation and voting power on standards committees to "consumers." What is possible is a representation mode filtered through government. Governmental members of standards committees, in a very generic sense, can be viewed as "representing" a consumer or public interest ...".

In his review of representation in the NFPA-, ANSI-related system, Dixon discusses their manner of classifying representable interests as well as "fairness surrogates for representation to achieve equivalent input from various interests." He concludes by stating: "Hence, although adequacy of informed input is always crucial, to try to achieve this in any very precise or detailed way through representation formulae keyed to committee membership and voting power is to chase a chimera for a variety of reasons ...."

Hoffman, S. David. "Underwriters Laboratories, Inc.'s Experience with Consumer Participation in Television Safety Standard Development." The Journal of Consumer Affairs, Volume 12, No. 2, Winter 1978, pp. 342-54.

This article describes UL's problems in identifying consumer representatives and its experiences with consumer representation on a committee preparing a proposed television receiver safety standard under CPSC's offeror process. The author states that: "Of all the categories of persons who were approached to work on the committees, the use- and technically- oriented consumer volunteers were by far the most difficult to find. Many persons who fall into these categories have full-time jobs, and are unable to take off time from work for meetings not involving their employment, particularly meetings covering a long period of time."

Many technically-oriented consumers declined to participate after they found out that consulting fees would not be paid. Conflict of interest criteria exclude a number of others. Use-oriented consumers needed technical orientation sessions to provide adequate frames of reference for the deliberations.

In the Committee voting, there were not substantial differences between consumers and non-consumers. The committee determined that an "unreasonable risk" did not exist and that a mandatory standard was not needed; nor would one have been cost-beneficial. Furthermore, a significant portion of the reasonable risk in television receivers could be eliminated by enhanced "...education of the consumer as to proper use and what constituted abuse of television receivers."

The author is Vice-President, Standards and Legal for UL as well as serving as Chairman of its Consumer Advisory Council.

Keitges, Pierre W. (President, National Committee for Clinical Laboratory Standards). Testimony for the Federal Trade Commission Hearing on Proposed Trade Regulation Rule on Standards and Certification. Washington, D.C., August 28, 1979.

NCCLS believes that the consumers of the products and services for which it writes standards are really health care professionals and not patients. The preponderance of its committee members are physicians, scientists, and laboratory managers and technicians. It contends that even publicizing its work to groups such as patients/consumers "who are outside the clinical laboratory field would be expensive and non-productive." Keitges stated that: "One must recognize that the vast majority of medical devices are designed to be operated by trained, knowledgeable users. Additionally, clinical laboratory results are received by medical personnel who interpret them in conjunction with other patient data. Standards related to medical devices are addressed to these users..."

Keitges contended that NCCLS costs would become "unbearable" if "members of the general public" had to be subsidized to serve on NCCLS committees.

Nichols, K. Guild. Technology on Trial: Public Participation in Decision-Making Related to Science and Technology. Paris, France: Organization for Economic Co-operation and Development, 1979.

The purpose of this report was to review for OECD member countries the complex and fluctuating nature of public participatory activities, to describe different national experiences and approaches adopted to cope with this phenomenon, and to analyze the various mechanisms designed to meet new demands and needs for public participation in decisions related to science and technology.

In its Conclusion, the report notes its admittedly numerous limitations. For instance, it states: "Most obvious is the fact that it raises more questions than it answers." and "More important, we have also not been able to explore

the precise nature of participation as seen and experienced by actual participants; we have examined the issue of public participation primarily from the perspective of government." In many ways, the report catalogues the kind of information that is NOT known about the topic.

The report also concludes that the very concept of "general public" is an amorphous one. The differences among the various constituent elements of the "general public" require a more careful analysis; especially an analysis of the interrelationships of the groups seeking increased participation in decision making. Groups such as labor unions now represented may well feel threatened by further representation by other "general public" groups such as environmentalists.

"Public participation is not, however, a universal phenomenon. There is, at the same time, a greater degree of 'activism' on the part of some groups and individuals and increasing apathy among others. Neither does this participatory phenomenon touch all areas of public policy; it is fluctuating, sometimes issues-oriented, and often apparently random." In effect, the OECD countries' experiences offer little concrete directions and lessons upon which to build an American program.

Peyton, Donald L. (Managing Director). Standardization and Consumerism. New York, New York: USA Standards Institute (now American National Standards Institute), May 7, 1968.

This is a reprint of the keynote address presented by Mr. Peyton at the 19th Annual Appliance Conference of the Institute of Electrical and Electronics Engineers. It represents a good historical view of how consumerism was seen by a typical individual active (then and now) in the management of a standards organization. In many ways, it shows how much progress standards organizations have made in reacting to consumer needs.

A few illustrative quotes follow:

* "The best design and most reliable manufacturing methods could well be meaningless in today's atmosphere of rampant consumerism unless qualified engineers are willing to put forth the additional time and effort required to develop standards which will ultimately aid the consumer."

* "Standards per se are too often dead, complicated, unimaginative, and at times useless technical documents...we must be willing to re-think the entire process and above all else to do a better job of "selling" the total voluntary standardization process to government (legislative and executive), to consumers, and indeed to many segments of industry."

* "First, we have failed miserably to use the standardization process as a communication link with consumers and government. Second, we have all failed to build a total voluntary standardization program --one which will link engineering, manufacturing, distribution, retailing, consumer information, and ultimate product utilization."

Winfree, Gwen. Consumer Participation and the ASTM Voluntary Standards Process - A Brief History and Evaluation With Recommendations. Philadelphia, Pennsylvania: American Society for Testing and Materials, March 1979. (Also excerpts appear in an article entitled, "Another Chair at the Standards-Writing Table - ASTM and the Ultimate Consumer", ASTM Standardization News, July 1979)

The report concludes by stating: "There is a recognized need to continue to develop concrete consumer policies as well as to improve existing programs, but ASTM may well be proud of its significant and historic contributions to placing the ultimate consumer at the standards-writing table." The word continue is especially significant. There is a very considerable body of historical evidence for ASTM's concern for the consumer which the author highlights.

For instance the report cites a 1923 address by ASTM's President at the Society's annual meeting which emphasized: "...the importance of maintaining an adequate representation of consumer interests at committee meetings to secure a real balance of producers and consumers in the formulation of standards and specifications."

Recognizing the logistical and financial problems involved in increasing the numbers of consumer representatives on committees, ASTM cooperated with ANSI in utilizing consumer sounding boards. Literally, this meant taking draft standards to consumers meeting in their home areas for consultation on their areas of concern without overburdening them with unnecessary technical debates. Operating within the Society's own stringent financial limitations, the consumer sounding boards and other ASTM activities indicate the Society's attempt to maintain the balance of interests on committees that it is publicly committed to.

Winfree states that: "ASTM must employ special efforts to attract a more diversified consumer grouping and give increased attention to recruiting women and minorities. All of these efforts must be undertaken with the understanding that it has not been enough to simply say, 'the doors are open (for consumer participation)'."She makes the following recommendations:

* "Policies for and implementation of recruitment plans for the ultimate consumer and other consumer involvement should be developed by the special committee appointed by the Board (as recommended in the previous section of this report)."

* "The implementation of these policies should be the responsibility of staff person(s) assigned specifically to provide support to this committee of the Board."

* "A media campaign should be launched to publicize these recruitment efforts, including a program like the Faculty-Intern Program for consumer reporters and related subject writers."

* "Proposals for funding consumer participation should be developed and submitted to private foundations and government agencies for one-time grants for specific projects."

V. CONSUMER INTEREST REPRESENTATION-- THE CONSUMER ORGANIZATION PERSPECTIVE

A. Overview

From both the available literature and interviews conducted for this study, common consumer concerns emerged regarding the issue of consumer interest representation in voluntary standards development. These concerns include the following four interrelated, key points. The first three points defend the necessity of consumer interest representation, which must be justified for FDA or another Federal agency to expend funds for such representation under Comptroller General decisions and in the absence of specific legislative authority. The fourth point effectively presents basic criteria for selection of representatives for funding.

- The "voluntary" standards development process creates product standards which are less and less frequently used by producers in a completely voluntary manner. Voluntary standards, per se, can have effects similar to those of regulations. To this extent, many standards should be considered a form of rulemaking and must have equivalent procedural and due process safeguards.
- Every victory for consumers already won in Federal decision-making must be a precedent for equivalent actions in voluntary standards development. These include such items as: open meetings, prior notice, justifications/rationale statements, public comment opportunities, and independent appeals procedures.
- Both government and private parties, who deal with consumer organizations must recognize the severe financial disadvantages under which the consumer organizations operate and take appropriate corrective action.
- A consumer representative must be more than an interested product user, it requires advocacy of the interest(s) of consumers. Underfunded, uncoordinated, token membership by individual consumers on standards committees does not constitute consumer representation.

On each of these four points there are clear differences of opinion between consumer organizations and the standards groups whose views were described in the prior chapter. Each of these points and the nature of the differences will be explored in this overview.

When considering FDA's proposed policy for the endorsement of privately developed standards, however, one significant caveat must be noted. It is the opinion of the Health Research Group (HRG) that the Medical Device Amendments (and their legislative history) do not allow FDA the option of endorsement. HRG believes that only standards, adopted with all of the due process requirements of the Administrative Procedures Act, are allowable and can adequately serve to protect the public health and safety. HRG's concerns are included among the common concerns only to the extent that they apply to

voluntary standards developed under the offeror process which would then be made mandatory by appropriate FDA action.

Voluntariness

An institutional consumer with long experience in dealing with voluntary standards organizations--the American Hospital Association--has been especially vehement in stating that consumers must be more involved in standards development since so little remains voluntary in our society today. (See Flanagan; annotated below). NCL members indicated that their participation in the Consumer Product Safety Commission's offeror process for standards increased their appreciation of how significantly standards do affect what is available in the marketplace. (See National Consumers League below). The Institute for Public Representation in its testimony to the Federal Trade Commission (see Smith below) gave an excellent, although legalistic, summary of the public implications of private standards.

Consumers are especially interested in voluntary standards used in lieu of regulation. Such standards do not currently afford them the due process safeguards legislated for regulations; however, standards enforced by the marketplace could result in a level of compliance equivalent to that of regulations.

These consumer perspectives are in clear contrast to the standards developing organizations' views that they are not, and should not be, responsible for what one or more government agencies do with their voluntary standards. This reflects a fundamental difference in how those two parties view the proper interface between the public and private sectors in our society.

Precedents

The Smith testimony (annotated below) discusses the direct relationship a consumer-oriented organization, such as the Institute for Public Representation, sees between procedural precedents in Federal regulations and the need for such safeguards in voluntary standards development. The correlation drawn between the kinds of records necessary to justify Federal rulemaking and those necessary for a standard is especially notable. The Thain entry also shows analogies between consumer participation on state licensing boards and participation on standards committees.

The two reports on the NCL/ASTM experimental consumer representation project show some of the ways in which experiences in Federal rulemaking have been carried over by consumers into standards development. For instance, NCL members on committee F-4 (Medical Devices) were responsible for getting the committee to establish the requirement that a rationale statement accompany all standards produced by that committee. This is clearly analogous to the background section accompanying proposed and final rules in the Federal Register and reflects the initiatives of Executive Order 12044 regarding justification for regulations.

Consumers, such as Robert Leflar of HRG and David Swankin of NCL, state very strongly that such procedural safeguards benefit the whole standardization

process and not just consumers. They contend that due consideration of the new insights and perspectives of consumers will result in better standards which are more effective and cost-beneficial to all parties involved. For instance, Swankin noted that a standard developed with full consumer participation is more likely to be a safeguard for a manufacturer in a product liability case.

The NCL statement at the FTC hearings on standards (annotated below) describes in some detail the kinds of procedural reforms in standards development which NCL believes are needed both to encourage more consumer participation and to facilitate the representation of consumer interests. An underlying concern in that statement and in other consumer materials concerns the need for financing.

As the U.S. Senate Committee on Governmental Affairs study (annotated in Chapter III) shows the importance of formal, procedural safeguards for consumers and others traditionally underrepresented in regulatory proceedings, it also emphasizes the importance of financing. Without adequate financing, the opportunities for enhanced public participation in rulemaking cannot be adequately realized. A report of an American Bar Association commission also recognizes the importance of financing parties with an interest in government decision making. The problem of financing consumer interest representation is clearly not unique to voluntary standards development; it pervades virtually every decision making arena where there is a consumer interest.

Financing

There was one point of absolute unanimity among consumer organizations: consumers cannot afford to fully participate in standards development, regardless of the regulatory relationships or significance of the standards. In effect consumer leaders argue that since the public interest is served by consumer interest representation, the government and/or standards organizations should pay for it either directly or indirectly. Such payments could be in the form of direct government subsidies or reimbursement programs to consumers or through payments to standards developing organizations which are passed on to consumers. The standards developers could also be required to pay for balanced representation of interests. Even though they feel consumers should be expected to make some contribution toward the furthering of their own interest(s), consumer leaders believe such a contribution must, of necessity, be almost token.

When interviewed, David Swankin made many positive comments about consumer representation funding at ASTM. (Reports on each of the two years of the ASTM experimental project with NCL are included in Section B.) In addition, Swankin was pleased with the results of the Department of Energy's indirect funding of consumers on the ASTM committee dealing with solar standards. (See Chapter III explanation) Swankin indicated that NCL was absorbing some administrative and participation costs as well as assisting ASTM in seeking foundation funding. These contributions added to NCL's credibility with the other committee members.

Representation

Some consumer organization staff who were interviewed indicated that the way some standards committees classified their members (according to interest(s) represented) was, at best, rather lax. This has had two detrimental effects

upon consumers. First, frequent misclassification of individual members as consumers serves to inflate the degree of representation of the consumer interest and make needed reforms seem less urgent. Second, overly general classifications, such as general interest member, tend to make it difficult for consumer organizations and individual consumers to contact and work with those committee members who are supposed to be furthering their interest(s).

All consumer organizations indicated that there was a substantive difference between a consumer who was merely a product user or (potential) beneficiary and one who was a knowledgeable consumer advocate. The Cohen article, annotated below, described a consumer advocate as "...part detective, working between meetings to dig out facts and scrutinize issues; part policy-maker, devising ways to solve problems and realize consumer-oriented objectives; and part negotiator, able to articulate a position but still recognize a satisfactory compromise." All interviewed objected to what one person referred to as "pulling a housewife out of a supermarket line and putting her on a committee writing standards for defibrillators as a consumer."

As the Cohen annotation notes, some of the Federal personnel currently serving on voluntary standards developing bodies are as wary of increased consumer participation as are industry members. This wariness is but one of the many reasons given by consumers as to why they must represent themselves and not rely on other parties, such as Federal employees, to represent their interests. Consumers are especially concerned when they perceive the Federal representatives as having a close, "revolving door" relationship to the industry whose products are to be the subject of the standards developed.

Although the above noted four areas of common consumer concerns are important to recognize, there are also differences which could affect the degree of success of any standards development effort such as FDA envisions in association with its endorsement policy. For instance, who should select the consumer representatives to be funded? NCL's General Counsel would leave the actual selection to the relevant standards developing organization with consumer organization advice. The Chairperson of NCL's Standards Committee believes that only consumer organizations should choose consumer representatives. HRG seems to believe that individual self-selection, through application for funding, is the best method. Depending upon how and by whom funding is to be provided, these differences could become significant variables for consideration by any interested Federal agency.

Although there is clear agreement on the need for funding, there is no agreement regarding how to actually disburse the funds. In standards development, Consumers Union (CU) has traditionally preferred Federal money to funding from private sources. George Papritz of CU stated that he would rather have funds for consumer representatives' expenses come directly from a Federal agency, such as FDA, than be passed-through a (possibly industry dominated) standards organization. Because CU, as an organization, rates specific products, it is extremely wary of having its members involved in any dealing remotely resembling a conflict of interest. Perhaps because it does not rate products, NCL would not have a problem with consumers receiving funds from a standards organization assuming, of course, that such disbursement was done under FDA guidelines.

CU is concerned with possible consumer conflict of interest vis-a'-vis the medical device industry. In contrast, HRG is concerned with possible consumer co-option from too close ties with FDA. No single FDA plan for funding consumer representation may ultimately satisfy all the concerns of all the consumer organizations interested in medical device standards. The same lack of consensus satisfaction by consumers might affect any Federal agency plan to fund consumer representation in voluntary standards.

The Frazier article, described in Section B, discusses the trends for increased health care at home which has clear implications for the role of consumers in the purchase and use of medical devices and consequently for their role in developing the preferable characteristics of medical devices.

B. Annotated Bibliography

American Bar Association, Commission on Law and the Economy. Federal Regulation: Roads to Reform: Final Report 1979 With Recommendations. Washington, D.C.: American Bar Association, 1979.

A portion of this far ranging and tersely written overview of Federal regulations concerns "The Need to Support Publicly Financed Participation in Certain Cases". It is reproduced below in its entirety (excluding footnotes):

"As private interests have gained increased rights of participation in administrative and judicial proceedings, it has become necessary to face the sensitive question whether agencies should financially support citizens or groups which claim to speak for interests whose representation could reasonably be expected to contribute substantially to a fair determination of the proceeding. These groups have special difficulties in financing their participation, partly because of the cost of raising funds from a large number of donors (the problem of large "transaction costs"), and partly because some are unwilling to contribute in the hope that others will bear the cost (the problem of "free riders").

"The proponents of publicly financed participation argue that certain regulatory agencies are unduly influenced by the advocacy of regulated industries whose expenses are deductible and whose resources far exceed those of other advocates. They must, however, confront the question whether the public interest is not already adequately served by the agency staff, which is provided at government expense for that very purpose. The debate has thus far led to a series of public financing experiments, which we endorse.

"The Comptroller General of the United States has issued opinions that certain agencies are authorized to finance the costs of some citizens or groups in agency hearings, and Congress has authorized the FTC to provide compensation for such participants in rulemaking proceedings. In a recent opinion the Comptroller General rejected the argument that participation must be indispensable to qualify for agency funding. He ruled that participation can be financed if it "can reasonably be expected to contribute substantially to a full and fair determination of the facts." This view of the Comptroller

General is consistent with the position of the American Bar Association adopted by the House of Delegates as its February 1977, Mid-Year Meeting.

> "RECOMMENDATION 9: The Commission supports the following resolution of the American Bar Association, which calls for: "The payment by government of attorneys' fees and other expenses, under proper limitations and controls, in administrative proceedings and in the judicial review of such proceedings, when the availability of such fees and expenses is necessary to assure the presentation of positions which deserve full and fair consideration in the public interest and would otherwise not be presented." Congress should appropriate funds for this purpose.

"The resolution emphasizes that attorneys' fees and other expenses would be paid only "when the availability of such fees and expenses is necessary to assure the presentation of positions which deserve full and fair consideration in the public interest and would otherwise not be presented." If, as usually would be the case, the agency administrator or staff believe that the agency can effectively present these positions, expenditure of public funds would be inappropriate. Where the agency staff would not effectively present these viewpoints, however, financial support of outside participation is warranted and should be funded by Congress.

"Procedures for the prompt selection of one or more eligible applicants are vital. If there is delay, organizations with limited resources should be permitted to begin participation while pursuing their application for reimbursement. The General Accounting Office and congressional oversight committees should review these procedures to assure that they comply with the relevant statutory provisions, neither discriminating against potentially effective organizations nor yielding to the importunities of organizations which would duplicate or triplicate the efforts of agency staff. The increased risk of delay from subsidized participation is in part offset by the prospect that such participants are likely to raise important questions for resolution early in the proceedings.

"Reasonable work standards should be established, and organizations able to do so should pay at least a portion of their costs of participation. To determine whether provisions for public financing accomplish their purpose, they should be authorized for a limited period and subjected to congressional oversight and other effective review."

Cohen, Rebecca. "Observations on ASTM Standards Writing: A Consumer's-Eye View." ASTM Standardization News, July 1979, pp. 19-21 and 49.

The author is deputy director of the Standards Committee of the National Consumers League. The article is essentially a means of reporting one aspect of the ASTM/NCL consumer representation experiment to ASTM members and of implicitly soliciting their further support.

The key point is that "...consumer representatives with undivided loyalty have a distinctive role to play by introducing new perspectives on old ideas and setting into motion processes that would otherwise languish. Furthermore, there is a difference between a consumer qua consumer and a consumer

advocate. The latter is part detective, working between meetings to dig out facts and scrutinize issues; part policy-maker, devising ways to solve problems and realize consumer-oriented objectives; and part negotiator, able to articulate a position but still recognize a satisfactory compromise." (underlining added for emphasis)

A further point of interest is the author's following statement: "Weak in numbers and flag bearers for an amorphous constituency, consumer advocates frequently find that the presence or impending presence of the government gives consumers bargaining leverage in debates with business interests or supplies the stimulus that gets new standards projects underway. That is not to say that consumer groups and government agencies always agree; it was a representative of FDA, for example, who could not fathom consumer participation on a medical device standards-setting committees."

Consumers Union of the U.S., Inc. Standards and the Consumer: A Special Report to the National Bureau of Standards. Mount Vernon, N.Y., November 12, 1964.

This 84-page report is an outgrowth of the activities of the Panel on Engineering and Commodity Standards of the Department of Commerce Technical Advisory Board. Early in its deliberations, the Panel judged that "the field of consumer product standardization is of such diffuse character that informed professional assistance would be required." In order to help provide such assistance, NBS contracted wih Consumers Union for a background report "which would outline the role of the consumer interest in standards of practice and define the general problem of considering the consumer interest in the formulation of standards."

The report represents an excellent historical overview of the relationships among standardization activities, the Federal government, and the consumer interest. Its value lies not only in showing where and how much the relationships have changed, but in showing the nature and kinds of underlying problems which have continued. In particular, the references to the need for standards developing organizations to consciously solicit "ultimate consumer" involvement and the problems of funding such involvement are noteworthy. (58 Bibliography citations.)

Cordes, Joseph J. and Settle, Russel F., Regulating the Voluntary Standards and Certification Process: An Economic Analysis (Testimony submitted to the Federal Trade Commission concerning the Proposed Trade Regulation Rule on Standards and Certification). Washington, D.C.: Public Interest Economics Foundation, July 31, 1979.

The proposed FTC Trade Regulation Rule included significant changes in the operations of the voluntary standards and certification processes. This paper was prepared for the Public Interest Economics Foundation to determine if the proposed changes were in the "public interest." Within its Policy Implications section, the paper contained a segment on "Financing Participation in Standards Development." The key highlights of that segment are the following:

"The FTC Staff Report gives considerable attention to funding of participation in standards development. We agree with this emphasis. Procedural changes such as those requiring representation on standards boards and adequate notification should improve participation by interests that are presently underrepresented. However, changes in the process alone will not fully overcome the free-rider problem described above. The proposed changes may lower the cost of participation in the standards development process. Nevertheless, the participation costs will remain high enough to discourage some individual interests from getting involved in the process, even though that involvement would yield aggregate benefits in excess of the aggregate costs of such participation. Consequently, a case can be made in the abstract for subsidizing the involvement of some interests in the standards development process...

"In private, for profit markets for well-defined goods and services, all financing (that is, sales) can be viewed as output-conditional: sales revenue is dependent upon demanders being supplied outputs they want at prices they are willing to pay. As long as certain other assumptions are met (involving competitive markets, reasonably well-informed buyers and sellers, low transactions costs, and resource mobility), this type of 'conditioning' arrangement yields private market outcomes that are in the 'public interest' (i.e., that are economically efficient).

"Analogous reasoning applied to the standards development process implies that, in order to encourage efficient outcomes, any financing arrangement should be conditional on those forms of involvement that would otherwise suffer from the greatest amount of underrepresentation. Specifically, the subsidy should vary with the 'quality' and 'quantity' of the 'output' produced by the subsidized involvement in the standards development process. However, financing arrangements that condition the subsidy on 'outputs' produced by greater participation will be difficult to design because of problems in defining operational measures of 'output.' These problems include the difficulty of measuring the degree of underrepresented demand, and the difficulty of determining when, and to what degree, increased participation in the standards development process actually alters the outcome in a 'desirable' fashion."

Flanagan, Robert J., Jr., Statement of the American Hospital Association: Testimony on the Proposed Trade Regulation Rule of the Federal Trade Commission on Standards and Certification, May 14, 1979.

The American Hospital Association (AHA) testified as an 'institutional consumer' of standards before the FTC. While its statement dealt largely with examples of procedural problems it had had with the National Fire Protection Association, its experiences may be typical of the types of institutional consumers the FDA would want to see involved in medical device standardization. The AHA summarized its position by stating:

"In many instances, the AHA favors standards-setting activities to be undertaken by voluntary entities rather than by government. We believe that, at its best, the voluntary system has the greatest ability to enhance accountability and to encourage innovation without sacrificing

effectiveness. We also believe, however, that in order to be fair and effective, the voluntary regulatory process must meet the same criteria for appropriateness, accountability, cost effectiveness, and public participation that we demand of government regulators. Unfortunately, our experiences to date with a number of voluntary standards-setting organizations has been less than satisfactory in this regard."

In its testimony, the AHA also criticizes many of the same things in standards development that an ultimate/patient consumer representative would be anticipated to be concerned about: lack of cost considerations, lack of written rationale statements, producer dominance of committees, and inadequate appeals procedures. If a well organized and well financed trade association with abundant technical resources to draw upon has trouble making its institutional consumer voice heard, what are the implications for ultimate consumer representation?

A few more quotes show the usefulness of the AHA experience when considering non-traditional interest representation in standards development:

"* We believe this (ANSI) 'canvas' method is designed to create an impression of consumer participation without providing adequate opportunity for meaningful input.
* The individual consumer is left powerless.
* These various procedures operate to frustrate the would-be consumer participant to the point where he is likely to become discouraged and give up the struggle.
* Unnecessary requirements imposed by just one activity of one standards development...have cost hospitals over a quarter of a billion dollars."

The 18 case studies and the 35 attachments to the testimony provide a wealth of background information for both FDA staff and consumer representatives serving on such standards developing committees.

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Frazier, Bonnie Nance. "Health Care at Home: A Booming Market." U.S. News and World Report. February 9, 1981, p. 68.

This article discusses the growing national trend toward health care in the home which increases both the number and percentages of consumers who are direct users of medical devices. Highlights of the article include:

"Since 1970, home health care has grown from a 500-million-dollar-a-year industry to one netting 2.5 billion dollars a year. By 1990, it is expected to reach the 10-billion mark.

"'We are taking the medical instrument from the doctor and putting it into the hands of the lay person,' say Frank Zorn, vice-president of Marshall Electronics, a medical-device company. 'This is not to circumvent the physician but to help people realize that taking care of their own health is an option.'

"Some surgical-supply companies that once sold mainly to physicians and hospitals are entering the public market. Medical House, a medical supplier in the Washington area that opened up its line to consumers two years ago, does 90 percent of its $500,000-a-year business with the public.

"As a result of consumer education, patients are asking more questions, seeking second opinions and taking a more active role in making medical decisions."

Of particular interest is the article's discussion of diagnostic devices where frequently consumer use is presumed to be marginal, at best. Frazier stated:

"Sales of diagnostic equipment are booming, especially the blood-pressure measuring device, spearheads of the industry, now netting 50 million dollars a year. In three years, sales of home pregnancy-test kits have grown 90 percent and are now a 35-million-dollar-a-year business. Find/SVP, a New York research firm, says that total sales of do-it-yourself diagnostic devices alone surpassed 100 million dollars by the end of 1980."

This change in the market structure for medical devices may have direct ramifications for the need for and the role of consumer representation in medical devices standards.

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Fusillo, Alice E. "Ethics and the Consumer Interest: Implications for Professionals in Government" in The Proceedings of the 25th Annual Conference of the American Council on Consumer Interests. Columbia, Missouri: American Council on Consumer Interests, 1979, pp. 215-219.

The author is currently a consumer affairs professional employed by the Food and Drug Administration and has spent 15 years with the Federal Government. The article analyzes factors in the organizational structure and functions of government which can work against professionals in their concern for the consumer's interest. In addition to "bureaucratic calcification", she cites a deficient centralized handling of consumer inquiries and complaints.

The article contains segments on: external pressures affecting consumer programs, specialized problems for consumer interests, mechanisms to increase consumer inputs, and disadvantages for the consumer. The author concludes with five recommendations "for the consumer's right to be informed, to choose, and to be heard". Included is the recommended establishment of a "consumer research group" within an agency which would utilize a representative sample of consumers as a means of gauging needed consumer input.

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Gellhorn, Ernest. "Public Participation in Administrative Proceedings." The Yale Law Journal, Vol. 81, No. 3, January 1972.

This is an analytical review of public participation that is widely cited as a

classic by Federal agencies and others in their comments upon the issues involved. Professor Gellhorn concluded his article by stating that:

> "The demand for broadened public participation in governmental decisionmaking rests on the belief that government, like all other institutions, rarely responds to interests not represented in its deliberations. An administrative agency is usually exposed only to the views of its staff, whose position necessarily blends a number of discrete public interests, and of private persons with a clear financial stake in the proceeding. The emergence of individuals and groups willing to assist administrative agencies in identifying interests deserving protection, in producing relevant evidence and argument suggesting appropriate action, and in closing the gap between the agencies and their ultimate constituents presents an opportunity to improve the administrative process.
>
> "...Agencies now have an opportunity to alter the course of events beyond their immediate jurisdictions because the ideal of broadened public participation is not limited to the administrative process."

Gelhorn's review of "eliminating barriers to effective public participation" in administrative hearings has direct relevance to barriers in voluntary standards development. Literally, changing his use of "public intervention" to "consumer participation" would update his analysis for FDA needs. For instance, such a change could be made in the following quote: "If public participation is in fact a 'right' which agencies have a mandate to foster, failure to render some (financial) assistance amounts to a practical subversion of that mandate."

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Leflar, Robert B. Statement to the Scientific Apparatus Manufacturers' Association. Washington, D.C.: Public Citizen Health Research Group, May 19, 1980.

When asked by the Association to present a "...consumerist viewpoint on FDA's 'voluntary standards policy' for medical devices...," Mr. Leflar made on overall assessment and then addressed three topics. On behalf of the Public Citizen Health Research Center he stated, "...we believe the FDA's 'voluntary standards policy' is unwise, violates fairness and common sense, and is, in fact, totally illegal."

Regarding the issue of when standards development is appropriate, he noted, "There is only a limited set of medical products for which even the best standards development is in order." His justifications for such a conclusion represent a significantly different and more resricted view than FDA has taken in its classification of devices into Class II.

Regarding the issue of what kind of standards ought to be written, Leflar noted, "...is there a place for voluntary standards? The clear answer: None whatsoever." He supports the issuance of only mandatory standards. In addition to his interpretation of FDA's legistative mandate in this regard, he cites concern about enforcement. "The marketplace is sufficiently forgiving, and the tort law and product liability system sufficiently capricious, so that

shoddy products will still be out there by the thousands injuring people, while certain less-than-upstanding companies continue to make a profit."

Regarding the issue of who should develop standards and how, Leflar favors either "an impartial standards-setting process: e.g., one carried out by the government, with auxiliary assistance from industry, consumers, researchers and health practioners" or the "offeror procedure" referenced in FDA's statute. His main concern is how all affected parties, especially consumers, are to be meaningfully involved. He concluded, "In summary, consumers have an independent interest in standards-development; they must be represented; and as a practical matter, since most consumers with the interest and expertise in these problems are extremely busy, to get good consumer representatives on these committees you have to do the things Dave Swankin of the National Consumers league was telling you about in the area of financial assistance."

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Leflar, Robert B. Testimony at Federal Trade Commission Public Hearing on Proposed Trade Regulation Rule on Standards and Certification. Washington, D.C.: Public Citizen's Health Research Group, August 22, 1979.

In his testimony, Mr. Leflar observed that: "Given the extremely limited staff and financial resources of public interest organizations, notice and opportunity to participate in the standards development process is virtually meaningless unless accompanied by provision of funding for participation." He further observed that "...FDA's proposed funding procedures for standards development effectively preclude meaningful consumer participation, even for those public interest organizations that are aware that a standards proceeding is to take place." (Emphasis is on the original.)

The tone of this testimony and the organization's reputation are such that FDA should expect the Health Research Group to adamantly oppose any standards development process or any particular standard whose development did not include significant, and adequately funded, consumer participation.

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Nader, Ralph. Prepared Statement Regarding S.825: Voluntary Standards and Accreditation Act of 1977. Washington, D.C.: United States Senate, Committee on the Judiciary, Subcommittee on Antitrust and Monopoly, April 18, 1977.

A significant portion of Mr. Nader's testimony is devoted to his contention that "the role of final consumers in setting product standards should be greatly expanded." The three following quotations summarize his views.

> "Trade standards group procedures for obtaining the participation of consumers and other independent interests are disgracefully inadequate. Industry representatives always far outnumber those representing consumers on committees where standards are written, the most important step in the standards-setting process. On the ANSI-NFPA mobile home standards committee, for example, manufacturer and supplier representatives make up 36 percent of the voting membership while consumer representatives comprise only 4 percent...Moreover, the industry's representatives have

the financial resources to attend meetings regularly, while consumer members can afford to attend only sporadically if at all.

"Besides their numerical underrepresentation, consumers also lack the preparation time and access to technical resources necessary for effective standards work. Industry representatives, who are paid for their standards work, have ample time and resources to prepare and support their arguments. In contrast, consumer representatives usually must work as volunteers.

"Both ANSI and UL rely upon 'Consumer Council' advisory bodies as their primary source of consumer input. But these councils are little more than public relations gimmicks. Their review of proposed standards comes too late in the process to have a significant impact. Only by active participation in actually writing a standard can consumers have a meaningful voice in its content. Moreover, most of ANSI's Consumer Council members are not even consumers! Instead, they represent producers or industrial and commercial intermediaries. The same is true for many of the members of UL's Consumer Council. ANSI's Council, for example, includes bogus consumer advocates such as representatives from the American Bankers Association, the Can Manufacturers Institute, du Pont, and Whirlpool. UL's 1976 Council roster lists representatives from corporations such as J. C. Penney, Woolworth, Sears Roebuck, and Lever Brothers."

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Nader, Ralph, and Maier, Peter. "The Case for Reforming Our Standards-Setting System." New Engineer, January 1978.

This article's precis noted that, "The lack of a voice for consumers and small-business representatives at national standards-setting organizations has led to anticompetitive practices and a stifling of innovation."

The authors recommend six reforms which would lead to a "...truly fair and democratic standards system." The first such reform would be to ensure "...full participation by consumers, small businesses, and other important underrepresented interests." They wrote:

"Consumers, small business, and other important groups now severely underrepresented must be included as active participants in the standards-writing process. Their vocal presence can help prevent narrow special interests from abusing trade product standards. Had the Z-21 gas appliance standards committee included a substantial number of consumer members, for example, it probably would have been more sensitive to the pressing need to conserve natural gas and to lower home heating bills.

"As a practical matter, financial assistance must be provided to representatives of consumers and small businesses. Unlike industry, these relatively impecunious interests often cannot afford to prepare for and attend committee meetings. Whether obtained from standards groups or the government, the financial aid should include both reimbursement for travel expenses and a per diem consulting fee.

"To participate effectively in the standards-writing, consumer representatives will also need access to advice from technical experts..."

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National Consumers League. Report on Consumer Representation in Voluntary Standards Setting: Year Two (1979). Philadelphia, Penn. American Society for Testing and Materials. March 1980. (Reprinted in ASTM Standardization News, April 1980, pp. 8-15.)

This is the second annual report of an experimental consumer representation project currently underway between NCL and ASTM. It summarizes accomplishments during 1979 and describes work plans for 1980 for five committees of ASTM including F-4 on Medical and Surgical Materials and Devices. Two notable NCL accomplishments on F-4 were involving other consumer groups and successfully pushing for a required "rationale statement" to accompany standards emerging from subcommittees.

The report also contains a section of observations and comments which attempts to draw lessons from the experiment. These range from the appropriate mix of consumer advocates and technical experts on committees to the organizational levels where consumer representation can be most effective. The report states: "Our experience continues to demonstrate that access to technical expertise is an essential ingredient of successful representation of any interest, including the consumer interests. While the nontechnical consumer representative has much to offer, his or her contribution is most certainly a limited one without technical support."

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National Consumers League. Report on the National Consumers League/National Bureau of Standards Conference. Unpublished, July 29, 1977.

The National Consumers League and the Department of Commerce National Bureau of Standards (NBS)'s Center for Consumer Product Technology (CCPT) sponsored a conference held June 8-9, 1977. Representatives of consumer organizations from around the country and Department of Commerce experts attended the meeting. The purpose of the Conference was to determine, by using the standards setting process as an example, how and when consumer involvement in federal decisionmaking could be effective.

The National Consumers League (NCL), through a contract with NBS, selected the conference participants and topics for discussion. In order to reach the widest cross-section of groups with the interest, time and resources to commit to participation, NCL contacted 265 national, state and local non-governmental consumer organizations. The groups were asked to indiciate their willingness and ability to perform a number of proposed follow-up activities, such as attending meetings, working on position papers, serving on standards committees, helping to locate technical assistance, and conducting consumer surveys. They were also asked to rank four possible topics of discussion according to their members' interests and needs.

Responses to the questionnaire showed that energy efficiency labeling and product performance labeling were of greater immediate interest than product safety and product standards to the largest number of groups. From among those who responded, NCL selected 18 consumer organizations to attend the scheduled conference and participate in the follow-up activities. Conference attendees discussed energy efficiency labeling and product performance labeling and the potential for consumer involvement in setting standards in the two areas.

The consumer participants at the conference made the following recommendations:

1. A pilot participation program must be established as a part of CCPT incorporating the suggestions for early consumer participation in standards development made during the conference.
2. An ongoing mechanism to exchange written or oral views must be established to facilitate a continuing relationship between NBS and the consumer community if the value of consumer's interest and participation is to be preserved.
3. The time and expertise of participating consumer groups must be funded in order to ensure the opportunity of consumer groups to participate in the process.
4. Consumers must be funded sufficiently to enable them to obtain technical support so they can participate effectively in technical decisions.

Points 3 and 4 reconfirm a consistent consumer emphasis on the need for funding in order to fully and effectively participate in government decisionmaking.

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National Consumer League. Statement on the Proposed FTC Trade Regulation Rule on Standards and Certification. Washington, D.C., June 28, 1979.

The League's Statement notes that: "We do not believe ... that there is anything inherently "bad" or "unfair" about standards. Nor is there anything unfair, per se, about having product standards set by non-government entities, or having them voluntary in nature." But, what they do object to are, what they consider to be, certain inherent problems in the current voluntary system. The League contends that: "If record keeping is inadequate (which it is), participation limited (which it is), substantive negative comments dismissed without adequate due process (which they are), and the consideration of alternatives discouraged (which it is), many, if not most instances of an unfair standard will be hidden."

The underlying conclusion of the League's recommendations to the FTC is that: "Standards development is expensive, and takes much time and talent." and "All the reforms we advocate will be ineffective unless the funding problem is overcome." Most major standards developing organizations already have a stated commitment to open their meetings to participation by consumers among other interests. Yet, NCL argues that: "Without the financial resources to

prepare and contribute to standards writing, the opportunity to participate could be no more than window-dressing, lending credibility to a standards writing system that continues to be dominated by producer interests, even though it may be superficially altered by our labors here."

Funding consumer participation not only creates additional costs for the process of standardization, it provides clear benefits. The best standards emerge from a full and open discussion of all possible alternatives by all interested parties. "It has been the experience of NCL that involving consumers in standards writing results in consideration of alternative approaches that, but for the presence of consumers, might not have been introduced and thoroughly discussed."

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Smith, Glenn C., Statement on Behalf of the Institute for Public Representation (Testimony before the Federal Trade Commission concerning the Proposed Trade Regulation Rule on Standards and Certification). Washington, D.C., September 11, 1979.

The Institute for Public Representation was founded by the Georgetown University Law Center and has the stated purpose of encouraging Federal regulatory and administrative agencies to recognize and consider the views of "various individuals or groups often ignored in the course of the administrative process." "...the Institute has actively supported proposals to establish participation compensation programs at numerous federal agencies." In its Summary of Statement, the Institute stated: "We recommend that standards developers be required to take affirmative steps to enhance the quality of notice and participation and that funding be made available for participation by underrepresented interests."

Smith sees the standards development process as an extention of the Federal rulemaking process and wishes to ensure the same kinds and levels of due process. He and the Institute support the FTC staff's contention that "... participation in the standards development process by consumers, small business, and others with limited resources has not been sufficient to adequately protect their specific interests." And, the Statement further notes that "...indirect representation of consumer interests by government officials, technical experts, and academicians has been similarly inadequate."

When analyzed in conjunction with the FTC's proposed Trade Regulation Rule, this document presents a very strong legal argument for well-funded consumer representation on any standards developing activity in any manner related to rulemaking. Regarding the need for funding, Smith argues that:

> "The economic and safety impacts of erroneous standards on consumers, small businesses and others, although significant in the aggregate, are even more difficult to assess and articulate to potential contributors than are the impacts of federal agency proceedings. Therefore, the ability of citizen advocacy organizations to raise funds for participation will be even more limited."

The document also contains useful insights on the question of representativeness.

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Swankin, David A. (Project Director). Report on Consumer Representation in Voluntary Standards Setting: A Report on the 1978 Demonstration Project Conducted by the American Society for Testing and Materials (ASTM) and the National Consumers League (NCL). Washington, D.C.: National Consumers League, December 1978. (Reprinted in ASTM Standardization News, July 1979, pp. 8-18.)

After more than two years of increasing discussions and cooperation, in early 1978 ASTM made a commitment of funds to support a systematic involvement by NCL members in selected ASTM standards developing committees. This experiment was seen as an opportunity to test and perfect ways of increasing both the extent and sophistication of consumer representation in standards development.

According to NCL, the project was "an opportunity to investigate and develop the methodology whereby a consumer organization could more adequately represent the consumer/citizen interest than unaffiliated individuals." Four basic questions were to be evaluated in the course of the project:

* What "mix" of lay consumer advocates and techncial experts is necessary on any particular committee?
* Do the technical experts need to be present at all meetings or can they advise the lay consumer advocates from a distance? What about the converse?
* Given limited resources, at what level can the consumer advocate function most effectively? Subcommittee? Task-group? Main committee? Executive committee?
* To what extent is the consumer representative required to play an adversarial role within a committee to be effective, and, conversely, to what extent is such a role ineffective?

The report makes observations and comments about the results of the first year of the experiment; these include:

* On each committee the appropriate mix is different. Not only that, it changes over time.
* There is no substitute for direct participation in the standards-setting process.... Paper review can never substitute for direct give-and-take.
* Based on our experience, a key to successful consumer participation is to have an executive subcommittee that is responsive to the idea of genuine consumer involvement. That is necessary whether or not the consumer representative is a member of the executive subcommittee itself.
* It is the conflict of ideas, not people, that assures the best standard.

* As more and more consumer groups become involved in standards-developing activities, there will be an increasing need to develop training materials and programs for them.

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Schultz, Mark. "Intervenor Funding: Taxpayer Rip-Off". At Home with Consumers: A Quarterly Consumer Information Journal. Vol. 1, No. 3, January 1980.

Mr. Schultz is a regulatory affairs attorney with the Chamber of Commerce of the United States. As the title of his article indicates, he opposes public funding for consumer participation in government decisionmaking. The core of his opposition rests on the following premise: "Every federal agency--whether an executive branch agency or an independent regulatory commission--has a statutory mandate to protect the consumer and, hence, the public interest. It is because of this mandate that the mechanisms for effective consumer protection and representation already are in place. The mechanisms simply need to be improved and made more visible."

In effect, to argue the need for paid consumer representation is inherently a charge that a Federal agency is not meeting its legal requirements. Schultz would prefer to reform agency procedures rather than pay consumers to participate in proceedings. The titles of three of the sections of his article indicate further aspects of his opposition: Potential Conflicts-of-Interest, Concept Deficient in Practice, and Abuses in Execution.

Schultz's arguments are typical of those raised in the private sector when any Federal agency attempts to fund consumer participation.

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Thain, Gerald J., et. al. Report of Survey of Public Members of Wisconsin Agencies and Advocacy of a Public Membership Requirement for Bodies Subject to the Proposed Rule. (Testimony before the Federal Trade Commission regarding the proposed Trade Regulation Rule on Standards and Certification.) Washington, D.C., The Center for Public Representation and The Center for Consumer Affairs, August 8, 1979.

Professor Thain and his colleagues presented a report dealing with public/consumer members on Wisconsin State Licensing Boards. It was designed to show direct analogies of how consumer members on standards developing bodies would describe the nature of their contributions to the proceedings and their patterns of interaction with the other categories of members participating. Their report concluded that:

> "Because there has been virtually no history of public membership on standards and certifying boards, any analysis of the advantages of requiring such membership must necessarily be based on "informed speculation" rather than empirical data. However, it is our belief that the data obtained from our survey of public members on various regulatory

boards in Wisconsin provides very persuasive support for the proposition that the public interest will be well served by having public membership on private standards and certification bodies."

The report describes the kinds of benefits that had occurred because of such public participation and noted that:

"Most of the public members perceived these benefits to derive from the fresh perspectives which these members have brought to their boards. Their comments reflected a belief that these benefits were more substantial than were any benefits gained from their performance of a 'watchdog' function regarding the professional members of the board."

Also, the report answers a number of questions/objections which had been raised concerning public participation. For instance, the report's survey indicated that "the supposed lack of technical expertise posed no effective barrier" to consumer participation. The authors argue that "token membership" should be avoided and that adequate commitments of resources are needed to realize the full benefits of consumer participation.

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Willett, Sandra L. "Consumer Representation in Government Decisionmaking: A Case for Public Participation Funding." At Home with Consumers: A Quarterly Consumer Information Journal, Vol 1, No. 3, January 1980.

As NCL's Executive Vice President, Willett is using this article to make a strong plea for funding of consumer participation. Her basic theme is that: "Public participation funding is an investment in our democracy." This investment is needed because: "NCL has seen over the years that an unbalanced public record based on narrowly represented interests renders government decisions elitist, naive, costly or impractical."

Most of the article is devoted to answering four "allegations"/"myths" that opponents of such funding frequently use:

* Consumer organizations want more laws and regulation at the expense of private initiative and competition;
* Any consumer can get public participation funding. The procedures are very loose;
* Public participation funding is a boondoggle for a select few; and
* The public participants simply support the agency staff position. They are "hired guns" of the agency.

Regarding the last "myth", Willett notes, among other things, that: "The record shows that in most cases the public intervenors have found FTC staff proposals to be ineffective, unnecessary, miscast, misdirected, incomplete, or otherwise unacceptable. Moreover, the public participants do not simply ask for tougher rules, rather they want more effective rules."

In concluding her spirited defense of funding, Willett stated that: "In opposing public participation funding which enables consumer representatives

to participate in government decisionmaking, many commercial interests are earning the unsavory title of "hypocrite". These same concerns vigorously oppose an independent consumer office in favor of agency-by-agency public participation programs".

VI. SUMMARY OF UNRESOLVED ISSUES

There are many different examples of Federal programs to fund consumer participation in the Federal decisionmaking process and of voluntary standards organization programs to increase consumer participation in voluntary standards committees. However, there remain a number of unresolved problem areas related to consumer participation programs in general as well as to the specific circumstances in which the Bureau of Medical Devices' program might operate. Of these areas, six seem especially significant and warrant further study. These areas and the related issues are summarized below in outline form.

I. METHODS FOR APPLICANT NOTIFICATION AND APPLICATION PROCEDURES

A. NOTIFICATION: The publication of a notice in the Federal Register may not be adequate for notifying many potentially interested consumers few of whom regularly (if at all) read the Federal Register. An organization might provide a notification service to its members, but consumers who are not affiliated with such an organization need other avenues of communication.

B. APPLICATION INFORMATION REQUIREMENTS: The type of information that an applicant is requested to provide is of major importance in any selection process. If too little or inappropriate information is requested, then the selecting group or official will not be able to fairly and accurately assess the competency of the applicants. On the other hand, if too much information is requested, applicants may be overwhelmed and decline to apply. There is also a need to avoid potential conflicts of interest and invasions of the applicant's privacy.

C. ELIGIBILITY CRITERIA: By developing and publicizing eligibility criteria, an agency can keep the number of applications from unqualified individuals to a minimum. The criteria can also be used by selection officials to quickly screen out any inappropriate applications that are submitted. The development of the criteria can be difficult; however, because care must be taken to comply with legal restrictions and at the same time prevent qualified applicants from being inadvertently eliminated.

D. NOTIFICATION OF SELECTION/NONSELECTION: That applicants should be notified that their application has been approved or rejected is obvious. Other questions (such as what types of information should be included in the notification, whether the reasons for acceptance/rejection should be provided to the applicant, or made public and in what manner made public) do not have obvious answers or have answers which may, on reflection, have negative consequences associated with them, such as the increased potential for adverse publicity and/or legal actions.

II. SELECTION PROCEDURES

A. SELECTION OFFICIAL/ORGANIZATION: The choice of the selecting official/organization can be crucial to the credibility of a consumer participation program and will also affect the amount of resources that may be required to implement and manage the selection process. In addition, the operating procedures and policies of each standards-writing organization may dictate more than one type of selection procedure.

B. SELECTION CRITERIA: In addition to basic eligibility requirements, selection criteria are needed if more than one eligible applicant is likely to apply. These selection criteria should cover all skills and types of experience that are necessary or useful for effective committee participation. Other factors of lesser importance or unrelated to a consumer applicant's ability to effectively participate may also be required. These might include trying to get balanced representation by age, sex, race, or geographical location. A particularly important factor may be an applicant's source(s) of funding and to what extent his or her operating budget comes from other Federal or state agency funds. A corresponding selection criterion could be the quality of an applicant's participation in other government proceedings.

III. REIMBURSEMENT POLICIES

A. REIMBURSABLE EXPENSES: In any reimbursement program, the question of costs which should or should not be eligible for reimbursement must be addressed. In addition, an appropriate rate for services which should be compensated must also be addressed.

B. RECORDKEEPING REQUIREMENTS: The nature of the arrangement entered into between a Federal agency and the applicant and/or outside selecting official will have a bearing on the types of financial records that must be maintained for potential General Accounting Office or agency audits as well as the types of records needed to evaluate the effectiveness of the program. In addition, procedures must be established to ensure that applicants/selecting officials are aware of such requirements.

C. FUNDING MECHANISMS: A crucial factor in the administrative burden, the degree of agency control, and type of selection procedures needed in a compensation program will be the choice of the funding mechanism. Funding mechanisms include grants, contracts, and cooperative agreements with one or more selecting organizations, or the funding of consumers by appointment as special government employees. Each of these mechanisms has advantages and disadvantages which must be explored.

D. FUNDING LIMITATIONS: The questions of whether limitations should be placed on the amount of money that any individual/organization receives in a given fiscal year needs to be addressed. While such limitations may ensure that more people/organizations are able to participate, they can also create problems if only a few individuals/organizations are qualified to participate.

IV. POLICIES IN THE FACE OF BUDGET LIMITATIONS

A. ALTERNATIVES: An agency which is unable to fund consumer participation in all committees must then establish policies to make the most effective use of the limited funds available. Alternative policies could include:

- Partially funding all qualified representatives;
- Placing tighter restrictions on reimbursable expenses;
- Funding participation only in selected phases of standards development;
- Having an agency staff member represent the consumer--either a technical staff member or a consumer affairs professional; or
- Limiting funding to selected high priority committees.

B. CRITERIA: If limitations are to be placed on funding, criteria must be established to choose the committees and phases of committee work which are the most crucial.

V. LEGAL AND CONGRESSIONAL CONSIDERATIONS

A. LEGAL PRECEDENTS: Any legal precedents that might limit the authority of an agency to conduct such a program should be explored.

B. CONGRESSIONAL CONSIDERATIONS: Questions such as whether such a funding program is premature in light of "intervenor funding" bills before Congress should be reviewed.

VI. ISSUES RELATED TO PROGRAM OPERATION

A. TRAINING: The types of educational materials and training that consumers will need to effectively participate in a standards development activity need to be researched, as well as the timing of such training.

B. EVALUATION: Whether the quality of a selected consumer representative's participation should be evaluated, what criteria should be used to make the evaluation, and who should be responsible for the actual evaluation must be addressed.

C. ROLE: The role of consumer representatives on standards-development committees must be defined, as well as the interest(s) that the consumer representative is supposed to represent along with his or her responsibilities in the presentation of information and in voting.

D. FDA PARTICIPATION: The need for FDA staff participation and the relationship between the FDA staff member on a committee and the consumer representative should be clarified.

E. AREAS OF COOPERATION: Both the Bureau of Medical Devices and the FDA Office of Consumer Affairs have a role to play in a consumer compensation program for standards-development committees. The areas of joint and individual responsibility should be defined.

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☐ Document describes a computer program; SF-185, FIPS Software Summary, is attached.

11. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here)

This report identifies for possible future study the major issues associated with the topic of consumer representation in the development of voluntary standards. The key terms (consumer and consumer representative) used in the report are defined, and background information on the Food and Drug Administration's medical device standards program is given. The report discusses important recent developments in consumer involvement in government and standards organization decisionmaking, and contains a review of Federal public participation programs. The literature on consumer representation is reviewed from the perspective of standards-developing groups and consumer organizations and the most salient documents are annotated. Based upon the available literature, supplemented by information obtained from personal contacts with affected parties, the major outstanding issues are summarized.

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