RULEMAKING ON A RECORD BY THE FOOD AND DRUG ADMINISTRATION

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For years the FDA has struggled through seemingly endless administrative hearings governed by an inefficient and time-consuming hearing procedure known as "rulemaking on a record." Two recent FDA proceedings, for example, consumed more than ten years from start to finish. Professor Hamilton suggests a number of reforms designed to streamline rulemaking on a record without requiring an amendment to the underlying statute.

I. INTRODUCTION

The Food and Drug Administration, an operating agency of the Department of Health, Education and Welfare, is one of the most prolific sources of rulemaking in the federal government.[1] Under the Federal Food, Drug, and Cosmetic Act[2] and other statutes, it is charged with regulating important and complex subjects on which Congress, of necessity, has given only general guidance.[3] The size of the industries

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This article is based on a report made to the Administrative Conference of the United States in December 1971 in support of recommendations made by the Conference's Committee on Rulemaking and draws on data current as of that date. The views expressed in the report and in this article are those of the author and have not been approved by the Committee or the Conference.

The recommendation actually adopted by the Conference is set forth in the Appendix.

1 *See* Austern, *Sanctions in Silhouette: An Inquiry into the Enforcement of the Federal Food, Drug, and Cosmetic Act*, 51 CALIF. L. REV. 38 (1963). Austern commented that the FDA probably has "the broadest powers of rulemaking found in the federal governement." *Id.* at 41.

2 21 U.S.C. §§ 301-92 (1970).

3 The principal areas of FDA rulemaking are:

(1) The establishment of mandatory standards of identity, quality, and fill of containers for foods;

(2) The regulation of food additives and the establishment of tolerance for deleterious substances in food;

(3) The regulation of many aspects of the drug industry to ensure that drugs available to the American public are safe and effective, and that adequate information is disseminated on possible dangers, side effects, and contraindications of prescription and nonprescription drugs;

(4) The determination of safe and suitable color additives for use in foods, drugs, and cosmetics;

(5) The determination of unsafe and hazardous household substances, toys, and articles for children under the Federal Hazardous Substance Act of 1960, 15 U.S.C. §§ 1261-62 (1970), and similar statutes, including the Child Protection and Toy Safety Act of 1969, *id.* §§ 1261(q), 1262(e)(1), and the Poison Prevention Packaging Act of 1970, *id.* §§ 1471, 1474(a); and

(6) The enforcement of the provisions of the Fair Packaging and Labeling Act, *id.* § 1454, to the extent that it applies to foods, drugs, and cosmetics.

subject to regulation[4] coupled with increasing public concern over the nation's health and physical well-being explains the widespread public controversy that has swirled around the FDA's regulatory actions.[5]

The FDA's broad rulemaking powers are hedged with an unparalleled variety of procedural restrictions.[6] Section 701(e),[7] which is the subject of this article, requires the FDA to hold formal evidentiary hearings before promulgating several important types of rules of general applicability. Detailed findings of fact based solely on the record must accompany the regulations, and such findings are subject to judicial review on a substantial evidence test. Rulemaking pursuant to the requirements of section 701(e) is often described as "rulemaking on a record" or "legislation by adjudication." In contrast, section 701(a) of the Act[8] gives the agency authority to promulgate regulations for the "efficient enforcement" of the Act without specifying any formal procedures. Where section 701(e) is inapplicable, the agency may proceed under section 701(a), and follow the simple, informal procedures of section 4 of the Administrative Procedure Act.[9] The agency has promulgated a substantial number of rules under section 701(a)[10] and

[4] The food industry alone has been estimated to account for about $125 billion of the nation's commerce. J. TURNER, THE CHEMICAL FEAST 3 (1970).

[5] Among the recent attacks on the FDA's performance are O. GARRISON, THE DICTOCRATS' ATTACK ON HEALTH FOODS AND VITAMINS (1970); HUNTER, CONSUMER BEWARE! YOUR FOOD AND WHAT'S BEEN DONE TO IT (1971); J. TURNER, *supra* note 4. Since 1962, numerous congressional committees have also criticized various aspects of the FDA's performance of its regulatory functions. *See, e.g.*, HOUSE COMM. ON GOV'T OPERATIONS, FIRST REPORT ON RECALL PROCEDURES OF THE FOOD AND DRUG ADMINISTRATION, H. R. REP. No. 585, 92d Cong., 1st Sess. (1971); HOUSE COMM. ON GOV'T OPERATIONS, THIRTY-NINTH REPORT ON THE REGULATION OF PRESCRIPTION DRUG ADVERTISING, H.R. REP. No. 1715, 91st Cong., 2d Sess. (1970); HOUSE COMM. ON GOV'T OPERATIONS, TENTH REPORT ON THE FOOD AND DRUG ADMINISTRATION PROCEDURE FOR SELECTION OF LABORATORY SITES, H.R. REP. No. 801, 90th Cong., 1st Sess. (1967).

[6] The Act contains a number of distinct grants of rulemaking power, and the procedural requirements vary to some extent with the type of authority granted. At least seven different hearing procedures are specified, some of which vary only slightly from others. There appears to be little reason or justification for this bewildering variety of procedures, which seems to have developed largely from historical accident.

[7] 21 U.S.C. § 371(e) (1970).

[8] *Id.* § 371(a).

[9] 5 U.S.C. § 553 (1970). These procedures are often described as "informal" or "notice and comment" rulemaking. The agency publishes a notice of proposed rulemaking, and provides an opportunity for interested persons to "participate in the rulemaking through submission of written data, views, or arguments with or without opportunity for oral presentation." After considering the matter submitted, the agency simply publishes the final rules, including "a concise general statement of their basis and purpose."

[10] Regulations issued under § 701(a) are sometimes considered "interpretative" rather than "legislative." The Supreme Court, however, has stated that these regulations may have the force of law and thus may be judicially reviewed at the outset. *See* Abbott Laboratories v. Gardner, 387 U.S. 136 (1967); Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967); Gardner v. Toilet Goods Ass'n, 387 U.S. 167 (1967). For a strong argument attempting to return § 701(a) regulations to "merely interpretative" status, see Cody, *Authoritative Effect of FDA Regulations*, 24 FOOD DRUG COSM. L.J. 195 (1969). *See also* Forte, *The GMP Regulations and the Proper Scope of FDA Rulemaking Authority*, 56 GEO. L.J. 688 (1968), *reprinted in* 23 FOOD DRUG COSM. L.J. 532 (1968).

clearly prefers to proceed under section 701(a) whenever possible.

The legislative history of the Food, Drug, and Cosmetic Act indicates that procedural restrictions on rulemaking authority were included in the statute for three reasons. First and foremost, many legislators feared that the agency might abuse broad grants of rulemaking power. Procedural restrictions were viewed as a check against arbitrary or capricious action.[11] Secondly, the debate on the bill took place only a few months after the Supreme Court's decision in the second *Morgan* case.[12] Many legislators, only dimly perceiving the distinction between adjudicating a specific right or claim and making rules of general applicability, felt that the procedural requirements of section 701(e) were essential to the validity of grants of rulemaking power.[13] Thirdly, the hope was often expressed that the elaborate procedural requirements and the threat of judicial review would force the administrators to act with a sense of responsibility and caution.[14]

Congress has granted new rulemaking powers to the FDA several times since 1938, and several of these statutes specify that the section 701(e) procedure must be followed.[15] In requiring rulemaking on a record, Congress may have felt it was merely following established legislative precedent for the FDA. However, industry pressure and a continuing mistrust of the broad grants of rulemaking authority that have been given to the FDA may also explain to some degree the imposition of these procedural requirements.

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11 The chairman of the committee presenting the bill stated that the committee proposed procedural requirements and judicial review as a "method of restraint against arbitrary action." C. DUNN, FEDERAL FOOD, DRUG AND COSMETIC ACT 851 (1938). He added that the bill gives the Secretary of HEW "more authority . . . than any white man ought to have unless with it there is proper restraint by the courts." Other statements refer to a "great branch of agriculture rapidly being destroyed by an arbitrary order of one man," *id.*, at 872, and "capricious and unreasonable" rules promulgated by an Acting Secretary "in misguided enthusiasm to protect the public health, well meaning but ignorant of what was involved . . . ." *Id.*, at 938.

12 Morgan v. United States, 304 U.S. 1 (1938). In *Morgan* the Court held that in administrative hearings of a quasi-judicial nature the party subject to regulation has a right to a full hearing, including the right to submit evidence and confront the claims of the opposing party.

13 *See* C. DUNN, *supra* note 11, at 852, 948, 1005.

14 *See id.* at 949-50.

15 Statutes requiring adherence to § 701(e) procedures include the Fair Packaging and Labelling Act of 1967, 15 U.S.C. § 1454 (1970), the Federal Hazardous Substance Act of 1960, *id.* §§ 1261-62, and the Color Additive Amendments of 1960, 21 *id.* § 706. The Drug Amendments Act of 1962, *id.* § 505, permits rulemaking on a less formalized basis. In the most recent statutes, the Child Protection and Toy Safety Act of 1969, *id.* §§ 1261(q), 1262(e)(1), and the Poison Prevention Packaging Act of 1970, *id.* §§ 1471, 1474(a), Congress in effect allowed the FDA to elect the procedure it would follow.

II. A Detailed Examination of Rulemaking on a Record by the FDA

As originally enacted, section 701(e) required a formal hearing on the record in connection with every rulemaking proceeding subject to that section. In the 1950's, however, the section was amended to eliminate the requirement of a hearing except when requested by an interested party.[16] As a result, section 701(e) now requires a formal evidentiary hearing only in a controverted rulemaking proceeding —where an adversely affected party requests a hearing and the agency concludes that he is entitled to one. These amendments have greatly decreased the number of formal hearings held by the FDA. Between 1960 and 1971, even though the overall number of rulemaking proceedings subject to section 701(e) numbered at least in the hundreds, the agency held only sixteen public hearings in section 701(e) proceedings.[17]

A. A Sketch of the Section 701(e) Procedure

A full-blown section 701(e) proceeding involves several discrete steps. First, the Commissioner conducts what is essentially an informal rulemaking proceeding. He publishes a notice of proposed rulemaking, setting forth the proposed rule and providing an opportunity for interested persons to comment in writing.[18] After considering the comments, the Commissioner publishes his "order" in the *Federal Register*, acting upon the proposal. This order may not be final, however, because any person adversely affected by it may file objections, and the filing of objections operates to stay the part of the order objected to. If no objections are filed, or if the Commissioner determines that the objections filed are legally insufficient,[19] he publishes a notice to that effect and the order then becomes effective.[20] The great bulk of rulemaking proceedings under section 701(e) end at this stage.

[16] Act of April 15, 1954, ch. 143, § 1, 68 Stat. 54; Act of August 1, 1956, ch. 861, § 2, 70 Stat. 919. These amendments are usually referred to as the Hale Amendments. Prior to these amendments, § 701(e) required FDA to hold a formal evidentiary hearing even though no one objected to the proposed rule. The legislative history underlying the present § 701(e) procedure is described in Forte, *Fair Hearing in Administrative Rule-Making: A Recent Experience Under the Federal Food, Drug, and Cosmetic and Fair Packaging and Labeling Acts*, 1968 Duke L.J. 1.

[17] During the fiscal year ending June 30, 1969, for example, sixty-four food standards were amended pursuant to § 701(e) without generating a single formal hearing. 1969 Department of Health, Education, and Welfare Ann. Rep. 71.

[18] 21 C.F.R. § 2.66(a), (b) (1971). The statute permits views to be expressed "orally or in writing." The regulations refer only to written submissions.

[19] *See* text accompanying notes 153-74 *infra*.

[20] 21 C.F.R. § 2.67(e) (1971). The regulations also provide for notifying a person whose

Where legally sufficient objections to an order are filed, the Commissioner conducts what is essentially a formal adjudicatory proceeding in connection with the stayed portions of the order. A full-fledged trial-type hearing[21] is conducted before an APA hearing examiner. "Any interested person" may appear and participate either in person or by representative.[22] As in a formal judicial proceeding, witnesses are sworn and may be cross-examined by any participant, objections are entertained to the admission or exclusion of evidence,[23] provision is made for interlocutory appeals,[24] and a stenographic transcript is made, which becomes part of the record for decision.[25] The presiding officer then prepares a report to the Commissioner complete with findings of fact and conclusions of law[26]—in other words a tentative, initial decision. On the basis of the record thus developed, the Commissioner issues a tentative order, complete with detailed findings of fact and conclusions of law on which it is based. Any party of record may object to the tentative order and request oral argument before the Commissioner, which he may grant at his discretion.[27] The Commissioner then publishes his final order, "based only on substantial evidence of record" at the hearing and containing the findings of fact on which the order is based.[28] Any person adversely affected by the order may then seek judicial review in the court of appeals for the circuit in which he resides or has his principal place of business. Findings of fact, if supported by substantial evidence, are conclusive, but the court has power to affirm the order, or set it aside in whole or in part, temporarily or permanently, and may order the Secretary of HEW to issue, amend, or repeal any regulation in accordance with its decision.[29]

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objections are rejected because they are regarded as insufficient.

[21] The statute itself does not specify what kind of procedures should be followed at the hearing. The legislative history of the Food, Drug, and Cosmetic Act of 1938, however, contains a statement that "while common law or jury trial rules of evidence need not be enforced at such a hearing, nevertheless it is essential to such a hearing that all the evidence on which the administrative officer acts be disclosed at the hearing and that the right to controvert *viva voce* be accorded. . . ." H.R. REP. No. 2139, 75th Cong., 3d Sess. (1938), *reprinted in* C. DUNN, *supra* note 11, at 824.

[22] 21 C.F.R. § 2.58 (1971).

[23] *Id.* §§ 2.58, 2.83, 2.88.

[24] *Id.* §§ 2.88, 2.89.

[25] *Id.* §§ 2.90, 2.92-.94.

[26] *Id.* § 2.96.

[27] *Id.* § 2.97.

[28] 21 U.S.C. § 371(c)(3) (1970); 21 C.F.R. § 2.98 (1971).

[29] 21 U.S.C. § 371(f) (1970). Section 701(f)(2) also provides that the petitioner may apply to the court for leave to adduce additional evidence, and, upon a showing that the evidence is material and that there were reasonable grounds for failing to adduce such evidence in the proceeding before the Secretary, the court may remand the proceeding to the Secretary for a further hearing.

The foregoing procedure, which involves all the steps of an informal rulemaking proceeding under section 4 of the Administrative Procedure Act and most of the steps of a formal adjudication, certainly must set some sort of record for cumbersomeness.

B. Rulemaking on a Record and the Food Standards Program

At present the FDA administers thirteen grants of rulemaking authority expressly subject to the section 701(e) procedure. Some of these grants, however, have never been exercised, while in others rules have been promulgated that have not been controversial or for some reason have not led to a public hearing. During the period from 1960 to 1971 the agency promulgated regulations pursuant to a formal hearing and the full section 701(e) procedure in only the following areas: (1) food standards pursuant to section 401 of the Food, Drug, and Cosmetic Act;[30] (2) labeling of foods for special dietary uses under section 403(j) of the Act;[31] (3) delisting of color additives pursuant to section 706;[32] (4) labeling of prescription drugs pursuant to section 502(n);[33] (5) classifying drugs as "depressant or stimulant" under section 201(v);[34] and (6) banning hazardous household substances

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[30] *Id.* § 341. This section authorizes regulations that establish a reasonable standard of identity, reasonable standard of quality or reasonable standard of fill of container for any food "whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers."

[31] *Id.* § 343(j). This section grants the FDA the rulemaking authority to require labels for such foods to contain the information relating to the vitamin, mineral, and other dietary properties of the food that "the Secretary determines to be . . . necessary in order fully to inform purchasers as to its value for such uses." The one rulemaking proceeding involving this section during the last decade, *Foods for Special Dietary Uses*, was the largest and most unwieldy rulemaking proceeding ever conducted by the FDA.

[32] *Id.* § 376(b). This section requires the Commissioner to maintain a list of color additives "suitable and safe for use" in or on food, drugs, or cosmetics. One proceeding, involving the delisting of certain coal tar colors, arose in the early 1960's.

[33] *Id.* § 352(n). This section authorizes the Commissioner to prescribe the information "relating to side effects, contraindications, and effectiveness" that must appear on labels of prescription drugs. One formal proceeding arose under this section during the last decade; during the same period there have been several amendments to the regulations under § 502(n), which were the subject of extensive negotiation between the FDA and the drug industry but did not give rise to a formal hearing.

[34] *Id.* § 201(v). This provision was repealed by the Comprehensive Drug Abuse Act of 1970, *id.* §§ 801-966 (1970). Two proceedings arose under this section during the preceding decade. Rulemaking authority under this section, however, was transferred to the Justice Department's Bureau of Narcotics and Dangerous Drugs on April 8, 1968, and these proceedings were completed by that bureau. Reorganization Plan No. 1 of 1968, 33 Fed. Reg. 5611.

The Comprehensive Drug Abuse Prevention and Control Act of 1970 requires the Secretary of HEW to provide a medical evaluation and recommendations on whether specific drugs or substances should be subject to that Act. These recommendations are "binding on the Attorney General as to . . . scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." 21 U.S.C. § 811(b) (1970). This Act does not define the procedures to be followed by the Secretary of HEW; almost certainly

pursuant to the Federal Hazardous Substances Act.[35] Of the sixteen formal rulemaking hearings held during the last decade, however, eleven involved rulemaking regarding food standards under section 401.[36] Because of the relatively large number of these cases, the powers and policies of the FDA relating to food standards should be considered in somewhat greater detail. The critical statutory language of section 401 is:

> Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container.[37]

Most regulations adopted under section 401 are "standards of identity" rather than "standards of quality" or "standards of fill of container."[38] A standard of identity provides a description of what may

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there is no obligation to follow the formal § 701(e) procedure, and, indeed, the Secretary may not even be required to follow § 4 of the APA.

35 15 U.S.C. § 1261 (1970). Under this Act, substances may be banned if the Commissioner concludes that the hazard involved is such that cautionary labeling would not be an adequate safeguard for the protection of the public. One formal proceeding involving carbon tetrachloride has been completed under this section, and a second proceeding, involving fireworks, is awaiting public hearing.

36 A twelfth hearing involving diluted orange drinks is awaiting formal hearings. On September 9, 1971, the agency republished three new proposals with regard to the stayed regulations, and asked for comment. 36 Fed. Reg. 18098 (1971). Two of these conflicting proposals were submitted by the Florida Canners Association and the National Juice Products Association. The third was a modified form of the FDA's earlier proposal.

37 21 U.S.C. § 341 (1970).

38 A standard of *identity* defines a food while a standard of *quality* establishes the quality characteristics of the food. For example, the standard of *identity* for canned peas states that "canned peas is the food prepared from one of the optional pea ingredients specified in this paragraph and water." There follows a list of four types of peas that may be used in the product "canned peas." 21 C.F.R. § 51.1(a) (1971). The standard of *quality* for canned peas, on the other hand, contains requirements such as "not more than 4 percent by count of the peas in the container are spotted or otherwise discolored," and "the combined weight of pea pods and other harmless extraneous vegetable material is not more than one-half of one per cent of the drained weight of peas in the container." 21 C.F.R. § 51.2 (1971). Standards of quality usually relate to matters such as tenderness, color, and freedom from defects. In practice, the concepts of standards of "identity" and "quality" are to some extent interchangeable since a standard of identity may incorporate elements of quality, *e.g.*, "canned peas" might be defined as a product containing less than .5% pods. *See* Austern, *Formulation of Mandatory Food Standards*, 2 FOOD DRUG COSM. L.J. 532 (1947). An important difference, however, is that a food that fails to meet a standard of quality may be marketed under a label that states, "Below Standard in Quality—Good Food—Not High Grade," 21 C.F.R. § 10.7(a) (1971), while food that fails to meet a standard of identity is deemed misbranded unless it is labeled "imitation." Standards of quality have been established for a variety of canned fruits and vegetables. *Id.* §§ 27.1-.131, 51.1-.990. Substandard commodities are widely sold to institutions, where the substandard nature of the food may be irrelevant to its use. In these situations of course, the ultimate consumer is unlikely to know that the food he is consuming is substandard, and indeed if he did, there is usually little that he could do about it.

be and what must be in the identified food. The Secretary of HEW may prescribe minimum or maximum quantities, or both. Food is deemed "misbranded" and subject to seizure if it either purports to be or is represented as a food for which a standard of identity has been established and it does not meet the standard. Illustrative of the effect of a standard of identity is the leading food standard case, *Federal Security Administrator v. Quaker Oats Co.*[39] Standards of identity had been issued for "farina" and "enriched farina."[40] "Farina" was defined as the "food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat" to a specified fineness. "Enriched farina" was defined as farina to which specified amounts of thiamine, riboflavin, niacin and iron were added; vitamin D, calcium, wheat germ and other optional ingredients might also be added. The Quaker Oats Company had for many years marketed a product consisting of farina with only vitamin D added. The packages of this product were truthfully labeled "Quaker Farina Wheat Cereal Enriched with Vitamin D" or "Quaker Farina Enriched with the Sunshine Vitamin." The quantity of vitamin D present in the product was also disclosed. As a result of the promulgation of the food standards, Quaker could not market its product either as "farina" (since it contained an ingredient not permitted by the food standard) or as "enriched farina" (since it did not contain all the mandatory ingredients for that food). The Court upheld the validity of the Administrator's regulation, noting that the "statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition."[41] The Act was intended to give consumers the assurance, the Court pointed out, "that they will get what they may reasonably expect to receive."[42] As a consequence of this decision, Quaker Oats may either (1) withdraw the product from commerce, (2) modify it so that it meets the food standard for either "farina" or "enriched farina," or (3) label the product either "imitation farina" or "imitation enriched farina."[43] It clearly may not

[39] 318 U.S. 218 (1943).
[40] 21 C.F.R. §§ 15.130, 15.140 (1971).
[41] 318 U.S. at 232-33.
[42] *Id.*
[43] *Id.* The FDA originally took the position that even a food labeled "imitation" might "purport to be" the standardized food and thus may be misbranded under § 403(g). The Supreme Court rejected this argument in 62 Cases of Jam v. United States, 340 U.S. 593 (1951), holding that an "imitation food" is not misbranded under § 403(g) if it is labeled as required by § 403(c). The *Jam* decision has been characterized as "a serious threat . . . to the exclusive appropriation concept" of the food standards section. 67 HARV. L. REV. 633, 661 (1954).

continue to market the product truthfully as "farina with vitamin D."[44]

The early food standards adopted by the FDA contained an exclusive list of optional ingredients that might be added to the food. The agency felt this practice was necessary to protect the public against unsafe additives; however, the practice had also discouraged innovations or improvements.[45] Since the 1958 food additive amendments, the FDA has had independent control over the safety of additives. It has been suggested that future standards should go no further than setting maximums for cheapening ingredients and minimums for expensive ingredients, and should permit food manufacturers to use any "safe and suitable" ingredient on the "generally recognized as safe" (GRAS) list. The FDA has recently followed this suggestion,[46] though consumers may be misled by emphasis upon "safe and suitable" optional ingredients that appear desirable but are in fact worthless.[47]

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[44] The argument that a product labeled "farina with vitamin D" might be deemed a different product than "farina" or "enriched farina" has been rejected. *See* Libby, McNeill & Libby v. United States, 148 F.2d 71 (2d Cir. 1945) ("tomato catsup with preservative" purports to be or represented as "tomato catsup"); United States v. 20 Cases, More or Less, Containing "Buitoni 20% Protein Spaghetti," 130 F. Supp. 715 (D. Del. 1954), *aff'd per curiam*, 228 F.2d 912 (3d Cir. 1956). In *Buitoni* the court held that "Buitoni 20% Spaghetti" purports to be or is represented as "spaghetti" even though "Buitoni 20% Spaghetti" has a history of separate identity going back 100 years prior to the formulation of any standards of identity for foods.

[45] Under present practice, a Government food standard usually specifies in detail the "recipe" required for the product. Improvements in any standardized food must therefore await a change in the Government standard, which may take many months or even years, before the improved food product can be made available to consumers. In addition variations from a standardized food are usually prohibited without a change in the standard under the interpretation that the standard is intended to encompass all similar products.

Because of this deadening effect on food technology, industry is encouraged to avoid the promulgation of standards, and to contest vigorously any proposed attempt at this form of regulation, which it might otherwise accept as reasonable and beneficial. Once promulgated, a detailed food standard of this kind impedes further research, hinders product improvement, and hence denies useful new products to the consumer.

WHITE HOUSE CONFERENCE ON FOOD, NUTRITION AND HEALTH, FINAL REPORT 122 (1969) [hereinafter cited as WHITE HOUSE CONFERENCE]. *See also* Comment, *The Federal Food, Drug & Cosmetic Act as an Experiment in Quality Control*, 20 SYRACUSE L. REV. 883, 903 (1969).

[46] The FDA first used this approach in establishing the standard for breaded shrimp. 21 C.F.R. § 36.30 (1971). The breaded shrimp standard specifies the minimum permissible amount of shrimp and permits any "safe and suitable breading ingredients" with a few exceptions. Similar flexibility appears in the peanut butter standard (permitting safe and suitable seasoning and stabilizing ingredients), *id.* § 46.1(c), and in the proposed standards of identity for sirups, 35 Fed. Reg. 15403 (1970). *But see* Weckel, *Research on Standardized and Unstandardized Foods in Educational Institutions*, 23 FOOD DRUG COSM. L.J. 474 (1969). The "safe and suitable" approach was approved by a panel of the White House Conference on Food, Nutrition and Health. WHITE HOUSE CONFERENCE, *supra* note 45, at 122.

[47] The FDA has begun to consider the desirability of nutritional labeling in lieu of the traditional food standards program. A panel of the White House Conference on Food, Nutrition, and Health has recommended that the FDA establish standards of nutritional quality rather than utilizing the traditional standard of identity, particularly in connection with new synthetic and convenience foods. WHITE HOUSE CONFERENCE, *supra* note 45, at 123-24. The Conference also recommended that more complete disclosure of in-

The FDA has promulgated food standards for twenty classes of food.[48] In the early 1950's, it was estimated that more than 50 percent of food dollars were spent for foods subject to mandatory standards.[49] Obviously, food standard decisions have had a major economic impact on the food industry. As a result, these decisions are often controverted and lead to formal hearings. In food standard proceedings, one industry or firm may be pitted against another industry or firm, with the FDA acting as a kind of umpire.

If a producer can persuade the FDA to standardize a common food so as to include his product and exclude his competitors' products, the producer has obtained the exclusive use of the common name of the food. For example, the standards of identity promulgated in 1946 for oysters required oysters known as *ostrea gigas* to be labeled "Pacific oysters" while other species could be labeled as "cove oysters" or merely "oysters."[50] Similarly, promulgation of standards of identity may compel producers to make major and expensive changes in producing or processing foods. For example, the food standard for peanut butter now requires the product to consist of at least 90 percent peanuts. Most peanut butter previously marketed consisted of between 75 and 87 percent peanuts. In this instance, the FDA lined up with a few consumer

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gredients should be required. Some of these new foods resemble traditional foods and have equal or superior nutritional quality, but are composed of entirely new ingredients. The FDA has published an industry proposal for a standard of identity for "Textured Protein Products," a product composed of vegetable proteins that resemble animal protein products such as fried bacon or veal cutlets. The product is defined partially in terms of mandatory nutritional characteristics. 35 Fed. Reg. 18530 (1970). Industry sources proposed the names "bontrae" or "tegretin products" with the hopes that these names might ultimately attain the same secondary meaning as the equally coined word "margarine." The FDA also has proposed on its own initiative a standard for "enriched macaroni products with improved protein quality" in terms of nutritional qualities. 36 *id.* at 4060 (1971). On nutritional labeling, see Baxter, *Nutritional Labeling: An Analysis*, 26 FOOD DRUG COSM. L.J. 82 (1971).

48 21 C.F.R. §§ 14.1-.14 (1971). An examination of these standards reveals that most deal with relatively simple foods. Modern convenience foods may be particularly difficult to standardize. For example, the FDA has struggled in recent years with a proposed standard for cherry pie. *See* 32 Fed. Reg. 15116 (1967), 36 *id.* 3364 (1971). For recent discussions of the food standards area see Hegsted, *Food Standards*, 24 FOOD DRUG COSM. L.J. 384 (1969); Austern, *Food Standards: The Balance Between Certainty and Innovation*, 24 FOOD DRUG COSM. L.J. 440 (1969); Goodrich, *Food Standardization—Past, Present & Future*, 24 FOOD DRUG COSM. L.J. 464 (1969).

49 67 HARV. L. REV. 632, 660 n.211 (1954).

50 This classification was held invalid on the ground that it was arbitrary and capricious. Willapoint Oysters, Inc. v. Ewing, 174 F.2d 676 (9th Cir.), *cert. denied*, 338 U.S. 858 (1949). The court stated:

> Permitting one segment of a seafood industry to enjoy the exclusive use of a term naturally associated with and normally applied to an article of food in common use under a common name without the most cogent reasons directly pertinent to the protection of the consuming public, appeals to us as being outside the bounds of reason and fairness.

174 F.2d at 697.

groups, while the affected industry generally opposed the proposed regulation.

New manufacturing techniques may require an amendment to a food standard if they are to be utilized. A process by which "cottage cheese" is manufactured by direct acidification rather than by the traditional culturing process may be economically practicable only if the product can be called "cottage cheese" rather than "imitation cottage cheese." Similarly, the usefulness of a process by which "parmesan cheese" may be cured in less than the ten-month period required by the current food standard may depend on avoiding the "imitation" stigma.

Decisions with respect to optional ingredients also may have substantial impact on producers of the ingredient or a competing ingredient. As described above, an ingredient, no matter how safe, may not be used in food unless it is permitted as an optional ingredient in the standard (or unless it falls into an area where a "safe and suitable" ingredient is specifically permitted). Thus, the manufacturer of dioctyl sodium sulfosuccinate, who believes the chemical to be a superior dispersant for cocoa, must first persuade the FDA to amend the standard of identity for cocoa before his product may be used by cocoa manufacturers. Also, required labeling of the presence of some optional ingredient may have far-reaching competitive consequences. The statement "emulsifier added" may reduce the attractiveness of a candy bar to customers; producers of fish oil (natural vitamin A) may strongly urge the FDA to require that the use of "synthetic" vitamin A in oleomargarine be disclosed as such to the customer, and so forth.

In many situations, the economic stakes in a food standard proceeding may be so great as to encourage parties to take full advantage of all procedural delays and opportunities for dilatory tactics.

C. *Rulemaking on a Record in Action: The* Peanut Butter *and* Foods for Special Dietary Uses *Proceedings*

During the last decade, the FDA has conducted two major section 701(e) proceedings that have been the subject of wide criticism. Both proceedings have taken (or will take) more than ten years from the formulation of the original proposal to the actual effective date of the regulation. Because they constitute the two most difficult proceedings conducted by the FDA during the period 1960 to 1971, I shall treat them in detail. They illuminate not only the problems the agency faces in all section 701(e) proceedings but also organizational and other deficiencies within the structure of the agency itself.

1. The Peanut Butter *Proceeding.*—The *Peanut Butter* imbroglio represents an attempt by the FDA to impose standards on an industry over its objections. Apparently the FDA decided to seek standards because of recognized variations in the peanut content of products labeled peanut butter and because a product marketed under a single name might vary widely in peanut content over a period of time.[51] Also, concern was felt over the undisclosed use of hydrogenated oils other than peanut oil.

On July 2, 1959, the agency published its original three-part proposal: (1) to define peanut butter as a food consisting of 95 percent peanuts; (2) to permit the addition or subtraction of natural peanut oil while processing; and (3) to permit five optional ingredients, including hydrogenated peanut oil, upon full disclosure of the presence of optional ingredients. This proposal was greeted with immediate opposition by the Peanut Butter Manufacturers' Association. At the time the two leading brands of peanut butter both contained about 87 percent peanuts and 8.5 percent hydrogenated oils.[52]

The agency received comments on the proposal, but more than two years elapsed before the order was published. As published on November 28, 1961, the order reduced the minimum peanut content to 90 percent and raised the ceiling on optional ingredients to 9 percent.[53] This order was stayed on February 1, 1962, and again a long delay ensued. More than two years later, on November 10, 1964, the FDA published a new "proposal," which differed from the stayed order in that it limited the overall fat content of the finished product to 55 percent and permitted as optional ingredients hydrogenated oils other than peanut oil; in other respects it closely followed the 1962 order, including the requirement that the peanut butter consist of at least 90 percent peanuts.[54] An order based on the revised proposal was published on July 8, 1965,[55] and stayed on September 4, 1965.[56] Six and one-half years had elapsed between the formulation of the original proposal and the public hearing. This delay is largely attributable to the relatively low priority given this proceeding within the FDA itself; the attorneys charged with the responsibility of formulating the FDA posi-

[51] At the hearing, one witness testified that a nationally advertised brand of peanut butter varied in peanut content over a period of time from 75% to 90%, without any disclosure to consumers. This brand also contained as much as 20% hydrogenated cottonseed oil.

[52] 24 Fed. Reg. 5391 (1959).

[53] 26 *id.* at 11209 (1961).

[54] 29 *id.* at 15173 (1964).

[55] 30 *id.* at 8628 (1965).

[56] *Id.* at 11349.

tion with regard to peanut butter content deemed other matters to be of greater importance.

The hearing in the *Peanut Butter* proceeding illustrates many of the problems the FDA faces in conducting evidentiary hearings in food standards cases. The main issue involved is relatively easily stated: Would it "promote honesty and fair dealing in the interest of consumers" to require peanut butter to contain at least 90 percent peanuts (as proposed by the FDA) or 87 percent peanuts (as proposed by the industry)? Subsidiary issues included whether a limitation on, and disclosure of, the use of hydrogenated oils in peanut butter would meet the elusive statutory test of promoting honesty and fair dealing, and whether the standard should be applied to peanut butter candies. As framed, these issues obviously involve political or economic value judgments, and only in the broadest sense are they factual questions.[57] Yet in its notice of hearing the FDA framed the issues in virtually these terms. An attempt to narrow the issues in the prehearing conference generated considerably more heat than light, as did an extensive colloquy at the beginning of the hearing itself.[58] As a consequence, a hearing procedure designed to develop and resolve controverted factual issues commenced on the broadest of economic value judgments. Illustrative is the testimony and cross-examination of the first Government witness. He presented a survey of cook books, patent applications, and the like dealing with the historical composition of peanut butter. At best, his testimony was peripheral and of such a nature as to render extended oral examination unnecessary. On cross-examination, the witness was asked about his personal tastes in peanut butter as well as about omissions in his list of patents, and about cook book formulations of peanut butter he had not referred to in his direct testimony. The first day of the hearing was devoted entirely to colloquy and the testimony of this witness; it developed practically nothing of value for the ultimate finder of fact and resolver of policy questions.

The hearing in this proceeding continued until March 15, 1966, and the transcript ultimately reached 7,736 pages. Of this material only a very small part is useful—the balance appears to be simply a monu-

57 *See* 1 K. Davis, ADMINISTRATIVE LAW TREATISE, § 6.06 (1958).

58 Colloquy also developed over whether it was permissible to consider two consumer-oriented proposals that were made in the comments to the order but did not appear in the notice of hearing. The proposals were: first, should specific sweetening ingredients be designated as optional ingredients; and secondly, should separate standards of identity be created for a product, "peanut spread," to consist of at least 85% peanuts, and "peanut butter," to consist of at least 95% peanuts? Counsel for industry strenuously argued that these were beyond the scope of the hearing, which must be limited to the proposal and order actually promulgated by the FDA.

ment to the normal desire of attorneys to ask questions and force minor "concessions" more verbal than real. A more cynical, but not implausible, explanation is that the peanut butter industry did not desire the standard to go into effect, and its representatives were therefore encouraged to "present a full airing of the issues."

Tentative findings of fact and conclusions of law were published on December 6, 1967, more than eighteen months after the hearing had ended.[59] The period for comments on this proposed order was extended to March 5, 1968,[60] and the final order was issued on July 24, 1968.[61] The order was then appealed to the Third Circuit, which did not hand down its opinion approving and affirming the regulations until May 14, 1970.[62]

2. *The* Foods for Special Dietary Uses *Proceeding.*—This proceeding involved rulemaking under both section 401, dealing with food standards, and section 403(j),[63] authorizing the Commissioner to establish such labeling requirements for foods that purport to be or are represented to be for special dietary uses as he deems "necessary in order fully to inform purchasers as to their value for such uses."

The original notice of proposed rulemaking was published on June 20, 1962,[64] citing only section 403(j) as a source of rulemaking authority, and proposing substantial revisions in regulations affecting vitamin supplements, mineral supplements, infant foods, foods for calorie-controlled diets, artificial sweeteners, hypoallergenic foods, foods for sodium-controlled diets, supplements providing specific nutrients, and foods offered as sources of protein. The most controversial proposal was to require labels for foods and supplements to refer only to specified ingredients in specified amounts. This was widely (and correctly) interpreted as an attempt by the FDA to restrict the permissible additives to those referred to, and to place lower and upper limits on additive amounts.[65] In devising this proposal, the FDA had two basic objectives: (1) to standardize vitamin-mineral supplements and certain vitamin-fortified and mineral-fortified foods in relation to recommended dietary allowances; and (2) to require certain label informa-

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59 32 Fed. Reg. 17482 (1967).
60 33 *id.* at 634 (1968).
61 *Id.* at 10506.
62 Corn Prod. Co. v. FDA, 427 F.2d 511 (3d Cir.), *cert. denied sub nom.* Derby Foods, Inc. v. FDA, 400 U.S. 957 (1970).
63 21 U.S.C. § 343(j) (1970).
64 27 Fed. Reg. 5815 (1962).
65 Section 403(i) requires labels to contain "the common or usual name of each . . . ingredient." 21 U.S.C. § 343(i) (1970). Limiting the names of ingredients that may appear on the label was thus a backhanded way to limit the ingredients themselves.

tion to give purchasers notice as to the actual nutritional value of such products. The FDA was concerned about products with widely varying components and the advertising of components that either had unproved nutritional value or were present in excessive or insufficient quantities to be of any nutritive worth.

The far-reaching implications of the proposals prompted a massive response. The FDA received more than 50,000 comments, although only 200 offered constructive criticisms and individual suggestions. The bulk were composed of stereotyped postcards and letters disseminated by the National Health Federation for its members to voice general objections to any FDA action.

On June 18, 1966, the Commissioner published his order.[66] While reflecting the purposes of the original proposal, the order bore little superficial resemblance to the proposal. It specified section 401 as the source of rulemaking in addition to section 403, proposed standards of identity for dietary supplements and vitamin and mineral fortified foods, and, most controversially, proposed a "crepe label" for all dietary supplements. The label was to read:

> Vitamins and minerals are supplied in abundant amounts by the foods we eat. The Food and Nutrition Board of the National Research Council recommends that dietary needs be satisfied with foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.[67]

In addition, the order limited the range of permissible statements and implications in connection with foods containing added vitamins or minerals. The FDA forbade making claims that the food had power to prevent or cure bodily ailments, warnings of vitamin deficiencies from ordinary foods, and statements that large segments of the American population suffer dietary deficiencies or that modern growing, handling and processing practices resulted in a loss of nutritive value of food.[68]

Again the FDA received numerous objections, and the order was stayed on December 14, 1966. The Pharmaceutical Manufacturers Association then filed suit in the District of Columbia District Court to

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[66] 31 Fed. Reg. 8521, 8524-25 (1966).

[67] *Id.* at 8525. After the publication of this proposed label, the National Research Council objected to the use of the name of that organization, and to the substantive content of the label. The label was then revised to read, "Vitamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements." *Id.* at 15730, 15732.

[68] *Id.* at 8525, 8527.

enjoin the proceeding on the theory that the June 18, 1966, order was not in fact based on the June 20, 1962, proposal but was new rulemaking that required starting over again with a "proposal." Essentially, the PMA argued that the proposal-comment-order sequence required by section 701(e) was intended to benefit the affected industry as well as the FDA, and that the procedure adopted by the FDA deprived the industry of an opportunity to comment on the proposal before it was formulated into an order. The district court refused to enjoin the proceeding,[69] and the court of appeals affirmed. Carefully appraising the purposes underlying the multistage section 701(e) proceeding, the court stated that the apparent purpose of the preliminary proposal-notice-order proceeding was to simplify the procedures applicable to a noncontroversial rulemaking proposal, and it was unlikely that such stages would obviate the need for a formal hearing where, as here, objections to the proposal were "fundamental and deep-seated." The court, however, rested its refusal to intervene primarily on the ground that the 1962 proposal embraced the essence of the 1966 order. Thus the objectors had already had an opportunity to comment on the issues presented by the 1966 order in connection with the 1962 proposal. The court concluded by stating that while the record does not reveal "a model of sure-footed administrative performance," the courts' function is to assure substantial fairness, "not to discipline agencies for awkwardness in their staff work."[70]

The decision of the court of appeals was released on June 16, 1967, but the notice of hearing was not published until April 2, 1968.[71] This delay resulted because the FDA's single hearing examiner was thought subject to attack for bias;[72] he had previously been in the General Counsel's office and had actively prosecuted a number of health food and vitamin supplement misrepresentation cases. An extensive search to employ another experienced examiner on a permanent basis proved unsuccessful,[73] and the agency finally employed a person with no prior experience as a hearing examiner. The new examiner had a long career as a trial lawyer with the Government, but virtually no prior exposure to administrative or rulemaking proceedings. His selection to handle

[69] *Id.* at 15730. Pharmaceutical Mfrs. Ass'n v. Gardner, 259 F. Supp. 764 (D.D.C. 1966), *aff'd*, 381 F.2d 271 (D.C. Cir. 1967).

[70] 381 F.2d at 282.

[71] 33 Fed. Reg. 5268 (1968).

[72] Other factors also contributed to this delay, including efforts to secure the testimony of expert witnesses for the Government.

[73] Because of the anticipated length of the proceeding, it was not deemed feasible to borrow an experienced examiner from another agency. See the comments of William Goodrich, Assistant General Counsel of HEW, 23 FOOD DRUG COSM. L.J. 338-39 (1968).

the most complex rulemaking proceeding the FDA had ever conducted was doubly unfortunate: not only was he unfamiliar with other agencies' practices in large public hearings, but his prior experience also tended to cause him to view the proceeding as a trial and the various parties to the proceeding as adversary litigants.

The prehearing conference finally convened on May 7, 1968. From the outset it was apparent that the hearing would be long and painful. More than 100 attorneys or independent parties filed notices of intent to participate. The prehearing conference met for ten sessions through June 11, 1968, and accomplished very little in terms of simplifying the issues or establishing expediting procedures. One morning passed with a parade of industry attorneys identifying themselves and their clients; another morning with the attorneys each giving a short speech favoring a minor proposal. At the conclusion of the second day, one experienced attorney stated on the record that the hearing was bordering on chaos, and proposed a number of procedural changes.[74] Because some attorneys were interested in only one aspect of the proposed regulations, a division of the hearing into phases on different portions of the stayed regulations seemed clearly desirable.[75]

Several problems plagued the hearings. As in the *Peanut Butter* proceeding, the actual hearing commenced with no clear delineation of the issues. The notice of public hearing had set forth the "issues" in general statutory language: "Whether it will promote honesty and fair dealing in the interest of consumers" to provide full information to consumers as to the value of foods for special dietary uses; whether the "crepe label" is a "necessary means of fully informing consumers of the value" of dietary supplements, and so forth.[76] The hearing examiner's inexperienced evidentiary rulings, particularly during the early part of the hearing, invited technical objections and wrangling among the attorneys. Also, a number of nonlawyers, particularly one medical doctor, actively participated and cross-examined Government witnesses at great length.

As the hearing progressed, several procedural innovations were attempted. These innovations improved the efficiency of the hearing,[77]

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[74] Many of the changes proposed were ultimately adopted; they added significantly to the effectiveness of the hearing. In reflecting on the decision to oppose these proposals, Government counsel commented that they were unfamiliar with these procedures and were uncertain of the consequences. Also, they were concerned that they might be required to present their entire case before they were prepared to do so.

[75] Ultimately the hearing was conducted in three phases: (1) infant foods; (2) vitamin and mineral supplements; and (3) dietary and low-sodium foods.

[76] 31 Fed. Reg. 15730-31 (1966).

[77] Many of these innovations were first proposed by the Government attorneys repre-

although several attorneys complained that they were prejudiced by them. These changes included: (1) submitting direct testimony in written form; (2) prohibiting cross-examination on cross-examination, or on other participants' cross-examination; (3) limiting the use of scientific texts and treatises to the contradiction of direct testimony, and requiring the cross-examiner to specify precisely the testimony to be contradicted and the contradicting passage; (4) limiting colloquy of counsel and legal argument unless specifically requested; (5) striking or limiting cumulative testimony of experts; and (6) prohibiting parties (other than the Government) from cross-examining witnesses of other nongovernmental parties without submitting a written statement to show that testimony was adverse to the opponent's interest. In connection with this limitation on cross-examination, the examiner tended to treat all opponents of the proposed regulations as having parallel interests and denied most requests to cross-examine, even in situations where the general positions of the two parties were clearly antagonistic, *e.g.*, producers of artificial sweeteners and sugar producers.

Despite the restrictions, most of the hearing consisted of repetitious and cumulative cross-examination of Government witnesses. Scientists and professional witnesses were asked to return on numerous occasions for additional cross-examination. One physician flatly refused to return; others, sensing a difficult and prolonged examination, simply declined to testify. Because the FDA has no subpoena power, the desired testimony was lost.[78]

When the hearing ground to a halt in May 1970, its tangible products had reached Brobdinguagian proportions. Testimony of Government witnesses accounted for about 25,000 pages of transcript—slightly more than two thirds of the total. The Government and the industry participants had proffered testimony of 162 witnesses and

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senting the agency at the hearing. In an effort to induce the hearing examiner to adopt them, the attorneys prepared memoranda for their immediate superior, the Assistant General Counsel of HEW, who in turn passed on the proposals to the FDA Commissioner. The Commissioner and certain of his subordinates (but not anyone from the office of Assistant General Counsel) then held conferences with the hearing examiner and directed him to institute the innovations. This indirect approach led to charges of impermissible *ex parte* contacts. *See* text accompanying notes 138-45 *infra*.

[78] In 1969, while the hearings were in progress, congressional committees and the White House Conference on Food, Nutrition and Health conducted hearings and studies indicating that many Americans suffered from malnutrition and starvation. In the FDA hearings, the agency was essentially contending that since the average American diet was satisfactory, there was no need for vitamin and mineral supplements. This apparent contradiction within the Government drew fire from the press, particularly when industry counsel attempted to introduce materials presented before the congressional committees and the White House Conference, and FDA counsel vigorously opposed the introduction of the evidence. This created the appearance that the agency was less interested in developing trnth than in preparing a partisan record to support preconceived erroneous conclusions.

more than 2,000 pieces of documentary evidence. When the examiner received proposed findings of fact in August, eleven of the industry participants pooled their efforts into a joint set of proposed findings, but because they did not fully agree, several submitted individual proposed findings as well. Twenty others filed their own briefs and proposed findings. On August 26 the examiner sent his report to the Commissioner on one phase of the proposed regulations—infant foods—but did not complete his report on the balance of the hearing until the following January.

The significance, length, and unprecedented number of problems created by this proceeding make it, along with the *Peanut Butter* hearing, a prime case study for needed improvements in the FDA's administrative processes.

D. Other Section 701(e) Proceedings

The *Peanut Butter* and *Foods for Special Dietary Uses* proceedings were the most drawn-out FDA rulemaking proceedings during the last decade. In each, the delay between original proposal and effective order is (or will be, in the case of *Foods for Special Dietary Uses*) more than ten years. In controverted foods standard cases, which make up the bulk of the formal rulemaking proceedings, the FDA did not complete *any* proceeding during the 1960's in less than two years, and the average delay was nearly four years (even leaving *Peanut Butter* and *Foods for Special Dietary Uses* out of the calculation). The delays encountered in proceedings not involving food standards are considerably shorter on the average, but even those delays have been criticized.[79]

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[79] H. HEFFRON, FEDERAL CONSUMER SAFETY LEGISLATION, A STUDY OF THE SCOPE AND ADEQUACY OF THE AUTOMOBILE SAFETY, FLAMMABLE FABRICS, TOYS, AND HAZARDOUS SUBSTANCES PROGRAMS 183-88 (1970).

The following tables illustrate the delays in § 701(e) proceedings of the past decade:

FOOD STANDARD PROCEEDINGS

	Notice to Order (months)	Order to Notice of Hearing (months)	Days of Hearing/ Pages of Transcript	Notice of Hearing to Proposed Findings (months)	Proposed Findings to Final Order (months)	Total Time Elapsed (months)
Orange Juice I	40	9	27/3434	23	11½	83½
Orange Juice II	9½	4	8/874	15½	7	36
Breaded Shrimp I	25	7½	9/1308	12	2½	47
Cheddar Cheese I	8	5	4/490	12	9	34

Delays in noncontroverted proceedings, on the other hand, are relatively short. For example, a noncontroversial proposal to permit the listing of fumaric acid as an optional ingredient under the standards of identity for fruit jelly was commenced on June 23, 1967.[80] No comments were filed and the order was entered on October 13, 1967,[81] to become effective on December 12, 1967.[82] The total time elapsed was less than six months. In contrast, a controverted proceeding (including a public hearing) on whether to permit artificial red coloring and cinnamon flavoring in the same jelly took nearly four years.

	Notice to Order (months)	Order to Notice of Hearing (months)	Days of Hearing/ Pages of Transcript	Notice of Hearing to Proposed Findings (months)	Proposed Findings to Final Order (months)	Total Time Elapsed (months)
Cold Pack Cheese Foods/Spreads	7½	8½	4/527	9	5	30
Fruit Jellies	2½	6½	2/234	27	19	55
Jelly	5	6½	2/399	36	10	57½
Peanut Butter	29	45½	30/7736	26½	8	109
Foods for Special Dietary Uses	48	21½	247/32,405	—	—	—
DSS in Cocoa	7	8	3/370	9	—	—
Parmesan Cheese	9	3	—*	—	—	—
AVERAGE	17.3	11.4	33.6/4777.7	17.8	9	56.3
			OTHER PROCEEDINGS			
Coal Tar Colors	5½	4	11/1374	5	—	—
Meprobamate	2	2	8/874	11**	7½	22½
Librium/ Valium	2	2	46/5167	36	21***	61
Carbon Tetrachloride	2½	11	6/484	11	5½	30
AVERAGE	3	4.8	17.8/1974.8	18.5	11.3	37.8

* Hearing actually underway on October 5, 1971.

** The proposed findings, tentative order, and final order were completed by the Department of Justice.

*** The Department of Justice conducted a supplemental hearing during this period that developed a transcript of 986 pages, taken over a 14 day period. Supplemental proposed findings were published 7½ months after the notice of hearing and the final order was published 2½ months after the supplemental proposed findings.

80 32 Fed. Reg. 8975 (1967).

81 *Id.* at 14205.

82 *Id.* at 17654.

E. Judicial Review

The legislative history of section 701(e) indicates that the formal hearing was largely directed toward facilitating ultimate judicial review. As a practical matter, however, judicial review has seldom been requested, and when the FDA has had to defend its regulations in the courts, it has generally won.[83]

Section 701(f)(3) provides that the administrative findings "as to the facts, if supported by substantial evidence, shall be conclusive."[84] In reviewing findings, the courts of appeal apply the same standard as prescribed in section 10(e) of the Administrative Procedure Act and the *Universal Camera* decision.[85] Thus, the courts have stated that substantiality must be determined "in the light of all that the record relevantly presents" and that findings must be set aside when the record "clearly precludes [the agency's] decision from being justified by a fair estimate of the worth of the testimony of witnesses or its informed judgment on matters within its special competence or both."[86] Also, while the court is not to abdicate the conventional judicial function, due regard must be given to the integrity of the administrative function.[87] "Given a range of reasonable alternatives, the administrator is given the task of selecting the one which, in his judgment, is most appropriate. In such circumstances, the court must defer to his judgment."[88] Thus the burden on a person attacking a food standard is a difficult one. He must show either that a finding is not supported by substantial evidence in the record or that given the facts found, the decision by the agency as to the standard promulgated was arbitrary, capricious or unreasonable. It is not enough for him to show that some standard other than the one actually promulgated was equally reasonable, or even that some other standard was more reasonable.[89] In view

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83 An informal count indicates that there are 200-odd standardized foods, the great bulk of which were established after a hearing (in part because many of them predate the Hale amendments). Only 45 food standards (representing 14 hearings) have reached the appellate courts; in 37 of these cases the courts have upheld the standards. Only a handful of cases have been remanded for further administrative proceedings on the ground that the Commissioner had made insufficient findings or that he had made findings with insufficient evidence of record to support them.

84 21 U.S.C. § 371(f)(3) (1970).

85 Universal Camera Corp. v. NLRB, 340 U.S. 474 (1951).

86 *Id.* at 490.

87 *Id.*

88 Corn Prod. Co. v. FDA, 427 F.2d 511, 515 (3d Cir.), *cert. denied sub nom.* Derby Foods, Inc. v. FDA, 400 U.S. 957 (1970). Similar statements appear in numerous other cases, including Cream Wipt Food Products Co. v. Federal Security Administrator, 187 F.2d 789 (3d Cir. 1951), and Willapoint Oysters, Inc. v. Ewing, 174 F.2d 676 (9th Cir.), *cert. denied*, 338 U.S. 860 (1949).

89 Willapoint Oysters, Inc. v. Ewing, 174 F.2d 676 (9th Cir.), *cert. denied*, 338 U.S. 860 (1949). Under section 401, the Commissioner may only promulgate "reasonable" definitions and standards of identity for foods.

of the amorphous nature of most factual issues in food standard proceedings and the wide range in which an administrative decision may be defended as reasonable, it is hardly surprising that the great bulk of standards subjected to judicial review have been upheld.

III. An Evaluation of Formal Evidentiary Hearings in FDA Rulemaking Proceedings

Rulemaking on a record by the FDA is unique primarily because of the formal evidentiary hearings at the culmination of the rulemaking process. In evaluating formal hearings, it is helpful to consider the justifications that have been put forward for them, and what functions, if any, they actually serve.

Most evidentiary hearings are designed to develop facts on which a reasoned decision may be based. In rulemaking proceedings initiated by the FDA, however, the agency obtains most of the facts underlying the proposed regulation and most of the facts on which opponents rely either before the notice is published or in the notice-comment-order stage of the proceeding. The formal hearings may originally have been justified partially on the assumption that they would develop factual information on which rulemaking would be undertaken, but since the Hale amendments in the 1950's, that information has been obtained primarily during the early stages of the proceeding.[90]

[90] When a manufacturer, rather than the FDA, has proposed a new food standard or an amendment to an existing standard, formal hearings have sometimes developed useful information for the agency. In these instances, the FDA may have less complete information than when it is proposing a standard or an amendment on its own motion. Generally, the more precise and technical the issue, the more useful the hearing is in developing new information. A good example is the *DSS in Cocoa* hearing, which was held on May 4-5, 1970. This proceeding was commenced by American Cyanamid, the manufacturer of dioctyl sodium sulfosuccinate (DSS), in an effort: (1) to amend the cocoa standard of identity to permit the use of DSS as a dispersant; (2) to amend the food additives regulations to permit the use of DSS in dry cocoa; and (3) to establish a tolerance for DSS in cocoa. The hearing was held on the single question whether DSS would accomplish its intended effect to rapidly disperse cocoa in dry beverage bases when mixed with water or milk. (The general safety of DSS in other uses had apparently been established, and was not in issue in this hearing). As the proponent, American Cyanamid had the burden of proof. At the prehearing conference, the position of the various parties became clear. The chocolate manufacturers stated that when they added DSS to their cocoa in their plants, the resulting product lacked desirable dispersant characteristics, and they stated that, therefore, they felt that DSS was not effective. However, they recognized that when American Cyanamid took their cocoa and added DSS to it, the dispersant characteristics of the resulting product were excellent. The Government attorney stated that the narrow issue was whether a product with superior dispersant characteristics could be produced by the average chocolate manufacturer, and added that it was "representing the consumer in the sense more or less in the nature of a devil's advocate, as it were."

At the actual hearing, the American Cyanamid witnesses presented samples and demonstrations of the cocoa produced by them, and submitted to cross-examination as to the techniques used in producing the product. Subsequently, representatives of the Chocolate Manufacturers Association testified that they could not duplicate the results obtained by American Cyanamid. Cross-examination was again productive as to how the tests were conducted. The hearing produced considerable helpful information about the manufacture

In the *Foods for Special Dietary Uses* hearing, the Government attorney described the evidentiary hearing as a nonadversary "fact finding excursion" designed to develop information that may be of assistance to the Commissioner. It is difficult to take this suggestion seriously; in fact, the attorney made the observation primarily to justify his position on a procedural question under discussion. Actually, the development of new information for the benefit of the agency seems only a minor purpose of the hearing.

The most obvious remaining justification for the formal hearing is that it provides a record for judicial review, enabling a court to determine whether there is substantial evidence to support the agency's findings. Because of the setting of the hearing and the types of issues involved, however, it is unlikely that this review provides a very meaningful check on agency action. The controverted issues in most FDA rulemaking proceedings involve broad economic or policy questions rather than particularized factual issues. In the *Peanut Butter* proceeding, the general consumer's notion of what the product "peanut butter" consisted of was bitterly controverted. In the *Foods for Special Dietary Uses* proceeding, the most basic question in dispute was whether the average American's diet rendered unnecessary the routine use of vitamin and mineral supplements. Conflicting or contradictory expert opinions and views on these questions are inevitable, and a court is unlikely to overturn the FDA's conclusion on such a broad question. Also, on the basis of certain "core" facts not seriously in dispute, the agency can usually justify several different policy decisions, any one of which the court will uphold. In the *Peanut Butter* proceedings, for example, once the agency showed consumer confusion and a product varying in content over a period of time, it was faced with a policy question, not a factual question. On the record made by the agency, it is unlikely that a court would overturn an 87 percent standard, a 90 percent standard, or even a 95 percent standard.

Since the FDA has usually taken a position on the broad policy questions before the hearing, the agency tends to view the formal hearing merely as a device for creating a record that will support previously determined administrative decisions. The FDA attorney at the hearing need not be particularly concerned with persuading the agency[91] of

of cocoa and the techniques by which cocoa is made dispersible in water or milk. In this instance, because the issue was the comparison of production techniques for a specific product, and the FDA did not have the burden of going forward, the trial-type hearing assembled important, if not essential, information that was probably not otherwise available to the FDA.

[91] The hearing examiner may or may not agree with the views of the agency on the

the correctness of the views he is espousing. He is reasonably confident that where a contradiction in views on a broad policy question arises, the agency decision will cite the views of the witnesses he calls rather than the contradictory testimony of witnesses called by other participants, and that the testimony will probably be sufficient to uphold the finding on judicial review.[92]

A somewhat different justification for the evidentiary hearing has been put forth by H. Thomas Austern, a leading member of the FDA bar. He suggests that section 701(e) proceeds on the theory that "he who regulates ought to appear publicly if there is a challenge and put on the table, subject to cross-examination, the facts on which he grounds his proposal."[93] While it might be thought that this, too, should ultimately lead to more meaningful judicial review, Austern denies that such review is meaningful. "Judicial review is largely a phantom," he writes. "In my own experience there are few courts that will second-guess the Food and Drug Administration, which has the reputation of protecting the consumer, the aged, the infirm, the ignorant, and the nursing infant."[94] The advantage of the proceeding is to give the industry on whom the proposed rules are being imposed an opportunity, by cross-examination, to point out to the agency that the factual assumptions on which the agency is proceeding are erroneous. In this view, the agency should approach the formal hearing not with the view of creating a formal record that will support by "substantial evidence" certain conclusions previously arrived at, but instead as an original trier of facts, without preconceptions, to determine which position is supported by a preponderance of the evidence. Also, under this view, what Government witnesses say on direct examination is not as significant as what they say on cross and what industry witnesses say on direct. The *Foods for Special Dietary Uses* hearing is often cited as an illustration of the need for this kind of check on agency factual assumptions.

There are problems with this justification for formal evidentiary hearings, though the argument cannot be rejected completely. In the

broad policy questions, or he may have no view on these matters. So long as the hearing examiner's report was not released to the public, his views on the questions in dispute could safely be ignored. The recent practice of making the report part of the public record, however, may alter the former free-wheeling approach of the FDA attorney, because, from his standpoint, it would clearly be undesirable for the hearing examiner to take a position directly contradictory to the agency's.

92 Of course, the findings must be supported by substantial evidence of record, taking the record "as a whole," and industry participants have sometimes complained that the FDA practice of relying on Government witnesses and ignoring contradictory testimony of industry experts fails to meet the *Universal Camera* standard.

93 Austern, *supra* note 48, at 451.

94 *Id.*

first place, there seems to be no reason that fundamental agency misconceptions cannot be corrected at the proposal-comment-order stage of the proceeding, except perhaps on the assumption that the FDA is singularly obtuse to written argument. Secondly, most agencies avoid factual misconceptions in rulemaking without a formal hearing, and there seems to be no reason that the FDA cannot do the same. Thirdly, an examination of what actually took place in the *Foods for Special Dietary Uses* proceeding casts doubt on whether the hearing actually served the suggested purpose. Much of the material that went into the record in that proceeding is cumulative or repetitious. Much of the testimony involved opinions of experts on which a firm consensus would be impossible to reach. An expert witness is unlikely to be shaken by cross-examination that requires comment on other statements by the same or different expert witnesses.[95] Under such circumstances, it seems unlikely that a formal hearing will result in correction of agency errors. Nevertheless, the agency was to some extent influenced by the testimony presented at the hearing in that proceeding, and while the overall effect is uncertain, the proceeding did breach to some extent the parochial confines of the agency.

The advantages of the formal evidentiary hearing thus appear to be elusive if not illusory. The disadvantages, in contrast, are substantial. The cost and delay of such a hearing has previously been outlined. The requirement that the FDA expert witnesses be produced for an often grueling cross-examination has tended to alienate the scientific community from the FDA. Further, the proceeding is so painful that the agency routinely seeks to avoid the hearing by negotiating a mutually acceptable compromise with the affected industry. The fact that there have been relatively few hearings despite the large number of rulemaking amendments indicates that this negotiation is usually successful. It is likely that the public interest has been compromised to some extent in this process, though precise documentation is not possible.

It is difficult to avoid the conclusion that at least for the FDA,[96] the formal evidentiary hearing should be abolished.

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[95] Helpful cross-examination dealt with the basis on which the expert witnesses formulated their opinions. Absent a major miscalculation as to the reliability of its witnesses, however, it is also unlikely that this examination would cause the FDA to change its views on basic questions.

[96] Rather surprisingly, the Department of Agriculture has successfully administered a program requiring rulemaking on a record for many years. Other agencies are also subject to a statutory requirement that rulemaking be on a record; the overall result is spotty. *See* Hamilton, Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Rulemaking (1972) (a study published by the Administrative Conference of the United States).

IV. Suggestions for Improving the Section 701(e) Proceeding

As a practical political matter, repeal of section 701(e) in the near future is unlikely. The large industries now subject to FDA regulation would almost certainly oppose any repeal effort vigorously.[97] The FDA must therefore adapt its current procedures to enable it to operate with maximum fairness and efficiency under its present statutory mandate.

Not all the FDA's difficulties in its section 701(e) proceedings can be laid at the door of Congress. There is considerable room for improvement by the agency itself. Practically everyone who has had any contact with section 701(e) proceedings has suggestions for improvement.[98] In June 1970 the National Commission on Product Safety issued a special report sharply critical of the agency's handling of proceedings under the Federal Hazardous Substances Act, and made a number of recommendations for improving enforcement of the Act.[99] A committee of the American Bar Association also studied the FDA rulemaking procedures recently and proposed a number of changes.[100] In the last few years, several conferences have focused on food and drug procedures, and many of the papers presented have contained specific suggestions for improvement.[101]

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97 Even though these industries bear part of the cost of the formal evidentiary hearings, they consider § 701(e) as a protection against unwanted regulatory proposals advanced by the FDA. The power to force the agency into formal evidentiary hearings may also be an important bargaining tool in negotiating with the agency.

98 *See* Hoffman, *Some Suggestions for Improvements in the Hearing and Rulemaking Procedures of the Food and Drug Administration*, 23 Food Drug Cosm. L.J. 465 (1968), *reprinted in* 21 Ad. L. Rev. 375 (1969). As Hoffman puts it, "Next to swapping horror stories about how arbitrarily and illegally the Food & Drug Administration treated their most recent clients, the favorite indoor sport of practitioners before that agency is suggesting improvements in its administrative processes." *Id.* at 465.

99 H. Heffron, *supra* note 79. The proposal included amending the Act to provide for a single, simplified administrative procedure, greater use of the FDA power to ban substances pendente lite, and a tightening of hearing procedures in order to speed up the administrative process. The final report of the National Commission on Product Safety summarizes these recommendations but does not make detailed recommendations for procedural improvements by the FDA.

100 The majority report generally favored proposals to judicialize further the hearing procedure. *See* Pendergast, *The Challenge to Improve the Hearings of the Food and Drug Administration*, 24 Food Drug Cosm. L.J. 154 (1969); Pendergast, *The Nature of Section 701 Hearings and Suggestions for Improving the Procedures for the Conduct of Such Hearings*, 24 Food Drug Cosm. L.J. 527 (1969). One eminent scholar, however, has argued that "some of this country's greatest administrative deficiences stem from lawyer induced overreliance on courtroom methods to cope with problems for which they are unsuited." Gellhorn, *Administrative Procedure Reform: Hardy Perennial*, 48 A.B.A.J. 243 (1962).

101 Most of these articles are published in the *Food Drug Cosmetic Law Journal* and the *Administrative Law Review*. The 1968 joint meeting of the food and drug committees of the Administrative Law and Banking and Business Law sections of the ABA resulted in the publication of the following useful articles: Byerly, *Some Common and Uncommon Hearing Procedures Under the Federal Food, Drug and Cosmetic Act*, 23 Food Drug Cosm. L.J. 457 (1968), *reprinted* in 21 Ad. L. Rev. 389 (1969); Forte, *General Principles of Administrative Rule-Making Under the Federal Food, Drug and Cosmetic Act*, 23 Food Drug Cosm. L.J. 476 (1968), *reprinted in* 21 Ad. L. Rev. 369 (1969); *Goodrich, The Food*

All of these proposals focus on the proceedings in which the FDA is the proponent of the proposed regulations and therefore must produce substantial evidence to support its proposal. While industry proposes numerous food standards and amendments to existing standards, in recent years relatively few of these proposals have gone to a hearing, and the agency has been the proponent in every problem hearing.

As might be expected, the suggestions coming from these various sources are often conflicting. All, however, start from the same premise: formal hearings in which the agency is the proponent are usually bitterly controverted. They are held only when all possibilities of conciliation or compromise have been exhausted, and when both sides regard the issues as sufficiently important to warrant the considerable expense of a hearing. As a consequence, the hearings are highly adversary in nature, and usually one or more participants is primarily interested in delay. Whether the hearing is described as adversary or nonadversary—and this characterization may affect the procedures followed—feelings often run high, and the battle is apt to be bitter. It is unreasonable to assume that all parties will immediately see the merit of specific suggestions that may expedite the proceeding.

Even though the formal hearings are adversary in nature, it does not necessarily follow that most of the trappings of a trial or administrative adjudication should be adopted. Nevertheless, arguments to this effect are often made. Members of the FDA bar, for example, desire broader discovery rights against the agency prior to hearings; they argue that these rights are necessary because the procedure is essentially adjudicatory and similar to a trial.[102] Other members of the same bar, however, object when government counsel seeks to restrict the scope of cross-examination of a government expert witness to his direct testimony, arguing that such "hypertechnical" rules have no place in nonadversary rulemaking proceedings where the object is to create a record containing the most accurate information possible.[103] FDA attorneys also have engaged in such essentially inconsistent reasoning. Such arguments by analogy are not only tendentious, but they also fail to recognize that the issues involved in these proceedings are often much

and Drug Administration's View on Procedural Rules, 23 FOOD DRUG COSM. L.J. 481 (1968) *reprinted in* 21 AD. L. REV. 383 (1969); Hoffman, *supra* note 98; Munsey, *Survey of Current Legal Problems in the Drug Area*, 23 FOOD DRUG COSM. L.J. 449 (1968), *reprinted in modified form under the title Antibiotic Certifications and the APA*, 21 AD. L. REV. 397 (1969); Pendergast, *Have the FDA Hearing Regulations Failed Us?*, 23 FOOD DRUG COSM. L.J. 524 (1968) (reply to Goodrich).

[102] *E.g.*, Hoffman, *supra* note 98.

[103] *E.g.*, Kleinfield, *The Food and Drug Administration and Nutrition*, 24 FOOD DRUG COSM. L.J. 308 (1969).

broader than those in the normal trial or administrative adjudication. This type of hearing is truly *sui generis*, and should be so approached.

A. Problems in the Prehearing Stages

The history of section 701(e) rulemaking proceedings demonstrates that serious problems plague the prehearing stages of the proceedings. Characteristic of these stages has been inadequate staff work, bureaucratic rigidity,[104] and most notably, excessive delays.[105]

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[104] In prior § 701(e) proceedings, deficiencies in the preliminary stages have included failing to consult adequately with interested groups before formulating a proposal, placing "bargaining points" in proposals on which the agency was prepared to concede, formulating proposals without considering the complexity of the possible hearing and similar matters. The agency is well aware of the mistakes it has made in the past and certainly will not knowingly make the same mistake again. Yet not all of the underlying causes of this poor administrative showing have been corrected. The Administrative Conference did not consider the following suggestions, but they were included in an appendix to the report supporting the adopted recommendation:

1. The agency should increase its efforts to secure information and data as to the subject of its rulemaking through informal means from persons in the affected industries, in scientific agencies, both in the Government and out, and consumer groups. In some instances publication of a notice that rulemaking is being considered may be desirable, but such notice to the public should be discretionary with the agency.

2. When formulating rulemaking proposals, the agency should limit the proposal to regulations it seriously intends at the time to adopt. The inclusion of proposals on which the agency later plans to recede should be avoided.

3. The agency should, to the maximum extent feasible, formulate rulemaking proposals with a view toward the complexity of the evidentiary hearing that may result. Whenever a proposal (1) involves a number of discrete and divisible proposed rules that are likely to be the subject of objection, or (2) affects a large number of different industries or firms in essentially different ways, the agency should, to the extent feasible, divide the proposal into separate rulemaking proceedings rather than publishing a proposal that may lead to a single massive hearing in which numerons conflicting interests may appear.

4. Current attempts by the agency to reduce unnecessary delay in handling the nonhearing portions of the section 701(e) proceeding should be encouraged. To the extent practicable, the General Counsel's office of HEW should concentrate formal rulemaking proceedings in one or more attorneys, depending on the overall volume of such rulemaking activities with a view toward reducing administrative delays.

5. If the agency makes substantial revisions to a published proposal, it should normally publish the revision as a proposal and invite further comment rather than issue it as a final order to which objection may be taken.

6. The agency should, to the maximum extent feasible, develop evidence about consumer beliefs or understandings by professionally conducted surveys.

[105] These deficiencies have been commented upon not only by attorneys practicing before the FDA but also by at least one appellate court and by a panel of the White House Conference on Foods, Nutrition and Health. Critical comments by attorneys are the most common. *See* note 101 *supra*. Similarly, the Court of Appeals for the D.C. Circuit was critical of the handling of the early stages of the *Food for Special Dietary Uses* proceeding. *See* text accompanying note 70 *supra*. A White House Conference panel, commenting on the lack of communication between the agency, experts in food and nutrition, and representatives of consumer interests, stated that "there is often little discussion among all interested parties in initial stages of Government consideration before proposal or promulgation of new regulations." Further, "[d]iscussion among consumers, industry, the Government, and other interested groups must be utilized to develop proposals, resolve issues, and minimize the need for formal and protracted public hearings." WHITE HOUSE CONFERENCE, *supra* note 45, at 124. These statements were obviously greatly influenced by the hearing in the *Foods for Special Dietary Uses* proceeding. The panel recommended that when the Secretary "wishes to propose a regulation on his own initiative or on the initiative of a petitioner, he should first consult with the Administration for Nutrition

Controverted hearings have led to delays that average about four years between the time of formulation of a proposal and the date the rule becomes effective. Part of this delay is attributable to the multistep proceeding required by section 701(e) and part to the nature of the trial-type hearing presently conducted by the agency.[106] Part of the delay not attributable to the formal hearings derives from time-consuming negotiations between industry and the agency. The industry may request time to conduct experiments or studies or to make surveys; the agency, in turn, is usually generous in granting these requests. Much of the delay, however, is attributable simply to administrative and bureaucratic slippage. One important cause of this delay is the relatively low priority the FDA staff gives to rulemaking proposals. Typically, such proposals involve no imminent danger to the general public health and present no deadlines within which the agency must proceed from one step to the next. As a consequence, rulemaking proposals generally have the lowest administrative priority.

The handling of food standard proposals illustrates the effect of poor organization in increasing delay. The Food Standards Branch of the Division of Food, Chemistry and Technology reviews the substantive aspects of food standard proposals.[107] The Branch's staff is quite small and delays in handling proposals are common.[108] Delays have also

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Science and Technology recommended by this Panel and other interested persons." The panel also recommended that a procedure be established for reviewing food standards proposed by industry and that consumer representatives be brought further into the rulemaking process. *See* text accompanying notes 150-52 *infra*.

[106] One commentator has suggested that the nature of the evidentiary hearing does not explain the long delays encountered, because the time spent in the actual hearings constitutes a very small part of the total delay. Pendergast, *supra* note 101. Pendergast suggests that the delays "are the result and perhaps the unnecessary result of lengthy internal deliberations at FDA. It is clear that the great delay that occurs so often between the promulgation of proposed FDA regulations and their publication in final form is very often the result of a lamentable tendency on the part of the FDA to hastily propose unscientific, incomplete, ill-considered 'shoot-from-the-hip' regulations which, after scrutiny by the industry and, in some cases, by the hearing procedure, require considerable revision and reconsideration. Perhaps more careful staff work before the hearing procedure ever begins, would be a better solution to FDA's problems than any broad-scale revision of hearing procedures." *Id.* at 531. It should be noted, however, that preparation for a full evidentiary hearing and development of proposed findings of fact supported by the record are all part of rulemaking on a record that are not present in rulemaking proceedings under § 4 of the APA. Thus, most of the delay in the period between the formal order and the proposed decision may be attributable to the requirement of a formal evidentiary heariug. Similarly, the delays between the proposed and final decisions also may be attributable to the peculiar requirements of § 701(e). Nevertheless the basic point is sound: many of the delays that have occurred in § 701(e) proceedings cannot be attributed directly to the formal hearings.

[107] The Food Standards Branch is a branch of the Division of Food, Chemistry and Technology of the Office of Sciences of the FDA's Bureau of Foods and Pesticides.

[108] In 1970, the director of the Bureau of Science reported that a "strict internal control system providing for frequent reporting to the Office of the Commissioner of the present status of each food standards project has been instituted. This system will permit

resulted from the organization of that part of the Office of General Counsel of HEW that handles food and drug matters, including the section 701(e) rulemaking proceedings. The staff of this office is small, numbering fewer than 20 attorneys. The office also handles seizure cases in the field, administrative adjudication proceedings, and provides legal assistance on general food and drug policy matters to the FDA Commissioner and the Secretary of HEW. Administrative rulemaking proceedings in this office also receive a relatively low priority, particularly in the nonhearing portion of the proceedings. An attorney assigned to a rulemaking proceeding may also be handling seizure cases and other matters of higher priority.[109] In addition, responsibility for the administrative proceedings is not concentrated in one or more of the attorneys, but is spread among the various attorneys,[110] contributing to inefficiency and delay.

B. Informal Opinions

After publication of an FDA rulemaking proposal, industry sources have often written the agency requesting clarification of the meaning of the proposed regnlations. The inquiries have often been posed as a series of hypothetical questions, with a request that the agency indicate how the proposed regulation would apply to each. The FDA answered about a dozen such inquiries in connection with the *Foods for Special Dietary Uses* proceeding; some of the responses satisfied the industry or firm so that they did not participate in the formal hearing. Agency representatives have sometimes appeared before trade associations and have been asked similar questions, which were later reduced to writing.[111] Similarly, in formal hearings participants have sometimes asked for clarification of the agency proposal, and when agency personnel

us to check into any unusual delay and eliminate the cause for delay, if possible." Lewis, *Food Standards*, 25 FOOD DRUG COSM. L.J. 74, 75 (1970). Discussion with personnel in the Branch in the Spring of 1971 indicated little, if any, improvement in lessening the delays.

109 For example, one attorney had simultaneous responsibility for two appeals in seizure cases, the highly controversial *Panalba* drug case, and the carbon tetrachloride rulemaking proceeding. H. HEFFRON, *supra* note 79, at 185 n.581. The attorney having primary responsibility for the *Foods for Special Dietary Uses* proceeding also was handling a food seizure case in Buffalo, and had about seven other active files. In both situations, the attorney worked on the rulemaking proceeeding when not involved with the other matters under his responsibility.

110 This practice gives each attorney experience in various facets of the office's operations but also tends to relegate rulemaking proceedings to a lower priority than if they were concentrated in fewer attorneys.

111 For example, in 1966 Commissioner Goddard appeared before the National Canners Association, where he answered a number of questions dealing with the proposed *Foods For Special Dietary Uses* regulations. A transcript of his remarks was later sent to Goddard for review, in the hope that his answer would save a number of the canners from having to file objections. The transcript was promptly reviewed and returned four days later.

have taken the stand, they have been cross-examined about how the proposed regulations should be construed.[112]

General interplay of this nature is desirable for both the agency and the industry. The process brings potential enforcement problems to the attention of the agency, which can then refine its proposal. Further, the areas of disagreement may be narrowed and the number of participants in the formal hearing reduced if the agency makes a suitable response. The agency, however, has sometimes been reluctant to respond to such requests on the theory that it may wish to "keep things flexible" or reconsider its regulatory position at a later date.

A regularized procedure for putting these questions to the agency would be desirable. Informal written opinions by which the agency describes the application of its proposal to a specific problem would appear sensible. Of course, to render this procedure fully effective, the agency should not decline to rule on submitted questions on the ground that they require a legal conclusion, but should state its position on the legal question. If the agency has not formulated a position on the issue in question, it should so respond.

The legal effect of such an "informal opinion" presents a perplexing problem without a completely satisfactory answer. On the one hand, the industry or firm may rely on the response by giving up an opportunity to participate in the section 701(e) hearing. On the other hand, if the factual setting changes, or if the agency was in error as to the facts, or if its views of its regulatory responsibilities change, it should not be frozen into an erroneous position by reason of its prior interpretation. One possible solution is to require that a change in a position previously taken in an informal opinion be preceded by notice of rulemaking and compliance with the section 701(e) procedure. This procedure, however, would create undue rigidity and, given this limitation, the FDA would probably refuse to give any informal opinions. Preferably, the agency might state in all responses to requests for interpretations: (1) that the views it is setting forth are its present position, given the specified facts as understood by the agency; (2) that its position may thereafter change in light of changes in facts or in its overall responsibilities; and (3) that before changing its position the agency will publish notice of the proposed change and interested persons will be given an opportunity to comment on it. In effect, changes in inter-

[112] Statements by such witnesses, however, may result in extensive cross-examination by affected parties even though the views expressed may not ultimately represent the position of the agency.

pretations under this suggestion would be treated as rulemaking under section 4 of the APA.[113] Responses to requests for interpretations should be made public as required by the Freedom of Information Act, and the agency should consider publishing the most significant positions in the *Federal Register*.

C. *Formulation of Issues Before the Hearing*

1. The Notice of Hearing.—An important cause of protracted evidentiary hearings is the failure to define and delineate the issues.[114] When the issues are undefined, the parties introduce and debate irrelevant evidence, cross-examination runs far afield of the actual points in controversy, and the examiner has little basis for excluding evidence or rejecting proposed areas of cross-examination.

The FDA's first opportunity to delineate issues for a section 701(e) hearing is in its notice of hearing. The agency has never taken full advantage of the "statement of issues" that is supposed to accompany the notice of hearing as a device to formulate the questions at issue in the hearing. Because the agency has the burden of supporting all portions of the stayed regulations by substantial evidence, it has generally framed the issues broadly enough to encompass all aspects of its subsequent proof. Thus most of the statements of issues published in the past have been framed in the language of the statute,[115] and have failed to clarify the specific issues in dispute.

Formulating detailed issues prior to the hearing requires a series of communications between the agency and the affected parties. The

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113 The Administrative Conference did not adopt this portion of my analysis, and the approved recommendation takes no position one way or the other regarding the legal effect of an informal opinion. The recommendation as approved appears in the Appendix, paragraph A.

114 In this and the following discussion with respect to the formal evidentiary hearing, I assume that the purpose of the hearing is a composite of the justifications previously suggested: to assemble factual information for the benefit of the agency, to create a record for judicial review, and to give affected persons an opportunity to examine and supplement the factual basis on which the FDA is acting.

115 Not all statements of issues have been framed in the language of the statute. Where the issue was relatively easily stated, considerably more precise statements have been employed. For example, in the *Coal Tar Colors* proceeding, the notice first described certain tests conducted by the FDA and the inferences the agency drew from them. The two issues were then stated to be: (1) were the FDA tests properly planned and executed; and (2) is it sound to exclude an additional ten colors without testing because of the chemical relationship of those colors to the tested colors. 24 Fed. Reg. 8065 (1959). Similarly, in the *DSS in Cocoa* hearing the issue was stated to be whether DSS would "accomplish its intended effect; that is, to rapidly disperse cocoa in dry beverage bases when mixed with water or milk." 34 *id.* at 19140 (1969). Such statements of issues are considerably more useful in delineating the scope of the hearing than ultimate issues posed in statutory terms, and the hearings in these two proceedings reflect the precision resulting from a clear delineation of issues.

agency's factual assumptions in formulating a proposal and the inferences it draws from these assumptions should be set forth in detail in the notice of proposed rulemaking.[116] Similarly, industry comments and objections to the order should be phrased in specific response to the agency's assumptions and inferences. Given the large number of preliminary steps before the section 701(e) hearing, the agency should be able to draft a reasonably accurate statement of the issues actually in dispute in its notice of hearing.

Issues that are narrowly framed need not be factual in nature; they may involve regulatory or policy conclusions to be drawn from facts that are not seriously in dispute. What is needed is a statement of the issues, either factual or conclusionary, to be considered at the hearing, defined as clearly and narrowly as possible.

There are difficulties in using the statement of issues for the purpose of defining issues. The advance formulation of issues is apt to be particularly difficult in areas such as food standards where there are no clearly defined legislative guidelines. It is always easier simply to use the vague language of the statute than to attempt to work out a more meaningful statement of actual questions at issue. Also, there may be a temptation to phrase the issues broadly in the language of the statute because of the fear that governmental testimony may subsequently be rejected on the ground that it is not within the issues as stated, or that a controversy may develop during the course of the hearing that was not recognized as seriously controverted at the outset. The nutritional status of the American public, which was a matter of serious dispute during the latter portion of the *Foods for Special Dietary Uses* hearing, may be an example of such a controversy.

The technical objections would disappear if the FDA would amend its regnlations to make clear that the statement of issues set forth in the notice of hearing is not to be deemed jurisdictional in nature and that further or substitute issues may be formulated during the prehearing conference or even during the hearing itself. The jurisdictional portion of the notice of hearing would then be the "statement of the provisions of the order to which objections have been made," and the agency would consider the balance of the notice as the first step in defining the issues.[117]

2. The Prehearing Conference.—There is general consensus that while the concept of a prehearing conference is good, in the FDA the

[116] In the last few years, the FDA has done this increasingly.
[117] The recommendation as approved appears in the Appendix, paragraph B.

prehearing conference has not worked as well as it should.[118] The precise reasons for this failure, however, are difficult to pinpoint.

The delineation of issues is probably the most important function of the prehearing conference. Yet in both the large hearings held during the 1960's, *Peanut Butter* and *Foods for Special Dietary Uses*, attempts to delineate the issues resulted in inconclusive wrangles between attorneys, and the hearings began without any significant clarification of the points of controversy. In *Peanut Butter*, inconclusive colloquy lapped over into the hearing itself.

Part of the problem may have been attributable to inexperienced hearing examiners or the general intransigence of the attorneys involved. Part of the problem may also have been due to the failure of the participants to prepare adequately. To be successful a prehearing conference must be directed by a person with some familiarity with the issues who is willing to insist that the participants isolate the areas of disagreement. Further, attorneys for the agency and the participants must have some knowledge of their own cases to isolate areas on which the hearing will focus.

Other agencies require all participants to distribute written statements of position at the prehearing conference. This procedure is permissible under the FDA's current regulations,[119] but was not used in any of the proceedings I examined. Routinely requiring these statements from all parties, including the Government, at an early stage of the prehearing conference would almost certainly improve preparation by the attorneys. The statements should include the names of the probable witnesses, the nature of their testimony, and a list of the documentary evidence the participant will introduce. The documentary evidence should be available for inspection and copying.

After distribution of the written position statements, the prehearing conference should seek to establish and define the precise areas of disagreement. The starting point normally should be the statement of issues set forth in the notice of hearing. Written objections or oral argument on these stated issues may aid in defining the issues actually in dispute. Normally the hearing examiner should reduce the statement of issues to writing and should seek to obtain the acquiescence of the parties that his statement reasonably defines the areas of disagreement. If

118 The ABA committee studying the FDA procedures recommended that the prehearing conference be more frequently and extensively employed to eliminate repetition, to obtain concessions on undisputed factual issues, and generally to require parties to disclose the nature of their case.

119 26 C.F.R. § 2.78 (1971).

agreement cannot be reached, the hearing examiner should nevertheless prepare a statement of the areas of disagreement as he understands them. In the absence of surprise at the hearing, the scope of cross-examination should be limited to the areas of disagreement defined at the prehearing conference.

In this connection, attorneys for the participants should not be permitted to object to all portions of the Government's presentation; instead, the hearing examiner should insist that they particularize the nature of their objections. If they are advised in advance that their right of cross-examination will be limited to the particular areas specified at the prehearing conference they might take this task more seriously.

At present, prehearing conferences are usually held on the record, with a verbatim transcript prepared. Possibly, preliminary parts of the prehearing conference should be held off the record to encourage informal discussion of the issues. As issues are delineated and recorded, however, it is desirable to have a verbatim transcript to record objections and comments. If a hearing is conducted in stages because it involves a number of divisible and complex issues, successive "prehearing" conferences, with the attendant establishment of areas of disagreement, should normally precede the hearing at each stage. Discretion in this regard should be vested in the hearing examiner. The prehearing conference should also cover other traditional functions of such conferences, such as identifying documents for admission into evidence, establishing hearing dates, setting deadlines for the distribution of written direct testimony, and determining the sequence in which witnesses will appear.[120]

D. Written Direct Testimony

At the beginning of the *Foods for Special Dietary Uses* proceeding, one participant proposed that all direct testimony be presented in written question-and-answer form. The government attorney originally

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[120] The willingness of the hearing examiner to permit departures from prehearing agreements has presented a significant problem in the past. While absolute rigidity is undesirable, a showing of substantial cause for the deviation should be required. In this respect, government attorneys have frequently insisted that deviations should be broadly permitted. For example, in the *Peanut Butter* hearing, the government attorney presented a list of witnesses and exhibits at the prehearing conference, but thereafter presented the case without regard to the information submitted at the conference. The list of witnesses was not followed, and the Government was permitted to introduce exhibits not shown on the original list. While some such variations may be necessary in light of developments at the hearing, the hearing examiner should sharply limit such practices.

The recommendation as approved appears in the Appendix, paragraph C.

opposed this as well as other procedural innovations suggested by the participant, but later reversed his position when the full magnitude of the problems presented at the hearing became evident. As a result, the direct testimony of about two thirds of the witnesses was presented in written form, with the witness being produced only for cross-examination. The response by the participants was uniformly favorable. Not only was there a substantial saving in time, but the attorneys were better prepared, and as a result the cross-examination was often more relevant and better directed. In the fall of 1971, the agency again utilized written direct testimony, in the *Parmesan Cheese* hearing.

In both *Foods for Special Dietary Uses* and *Parmesan Cheese,* the government witnesses were produced for cross-examination before the industry witnesses' direct testimony was submitted. Preferably the parties should be required to submit all direct testimony before any witnesses are produced for cross-examination. The tendency by some participants to develop their case through cross-examination would thereby be minimized. Generally, the proponent's testimony should be distributed, followed by a period of time for the opponents to submit their written direct. Thereafter, the proponent's witnesses should be produced for cross-examination, followed by the opponent's witnesses. Written direct testimony should be accepted either in question-and-answer or narrative form. In some situations, it may be preferable for the witness to supplement his written direct with a short oral presentation. This procedure may be appropriate, for example, when the witness is introducing samples.[121]

E. Restrictions on Cross-Examination

Virtually unlimited cross-examination is the most obvious distinguishing feature of a formal section 701(e) proceeding. In the past, excessive, redundant, and unrewarding cross-examination has been a major cause of protracted hearings, and it is doubtful whether facts developed on cross-examination have ever materially affected the outcome of a section 701(e) proceeding.[122] Cross-examination, however, is

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121 The recommendation as approved appears in the Appendix, paragraph D.

122 On the other hand, there is impressive unanimity of views as to the importance of cross-examination among most attorneys practicing before the FDA. In their eyes, the privilege of cross-examination is the most important check against arbitrary administrative action. *See e.g.,* Forte, *supra* note 101. One attorney with a major Washington, D.C., law firm, for example, stated that he became absolutely persuaded about the desirability of free cross-examination because of an incident during the *Foods for Special Dietary Uses* proceeding. He stated that the hearing examiner first became aware of the serious logical difficulties in the FDA's position with regard to the "crepe label" only by reason of search-

an integral part of the formal section 701(e) proceeding as presently constituted, and could probably be eliminated only by statutory amendment.[123]

Cross-examination in the hearings I examined tended to be repetitious or cumulative; when concessions were wrung from witnesses (often after pages of close questioning), they seemed minor or even trivial.[124] As would be expected, when the issue is clearly defined and relates to specific facts rather than to general economic judgments, cross-examination has usually been helpful. In the *Foods for Special Dietary Uses* proceeding, for example, the government counsel concedes that careful cross-examination about the FDA's consumer attitude study—the way the sample was obtained, the types of questions asked, and the tabulation of responses—helped place the survey in its proper perspective as evidence. In this regard, it should be noted that this cross-examination was conducted by a lead attorney selected by agreement among the participants. On the other hand, when the issues are not clearly defined, or when they involve broad questions of policy rather than facts, cross-examination is apt to be rambling, unfocused, and not very helpful. Much of the cross-examination in the *Peanut Butter* proceeding, where the issue was defined as whether peanut butter should consist of 90 percent or 87.5 percent peanuts, fell into the latter category.

Implementing recommendations for prehearing isolation of issues and prior distribution of all written direct testimony should help render cross-examination more useful. Attorneys who have prepared and submitted their direct testimony may feel it unnecessary to develop their position further by cross-examination of adverse witnesses. Areas of disagreement and the positions of the various parties may be more sharply defined. Nevertheless, the overall impact of these recommendations on cross-examination is problematic; direct restrictions on cross-examination may also be necessary.

Limitations on cross-examination should eliminate repetitious,

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ing cross-examination of an expert on hunger and malnutrition in the United States. It is quite possible that the attorney's recollection of this cross-examination is accurate, although I was unable to verify it from reading the cold transcript.

123 The last two sentences of § 7(c) of the APA read as follows:

> A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rulemaking . . . an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

My position is basically that a participant would be prejudiced if he is totally prohibited from cross-examination where factual issues exist. *See* Baldor Electric Co. v. Wirtz, 337 F.2d 518 (D.C. Cir. 1963).

124 Questioning by nonlawyer participants was singularly unproductive.

irrelevant, immaterial or cumulative testimony. Such restrictions must rest ultimately on the discretion of the hearing examiner, who must balance the possibility that a restriction truly prejudices a participant against the need for expediting the hearing. In some situations, restrictions on cross-examination may create so many objections that it would save more time simply to permit the questions.

It is usually impossible for a hearing examiner to judge the potential value of cross-examination until after he has heard some of it. Generally, if the cross-examination does not relate to the areas of disagreement defined in the prehearing conference, the hearing examiner should bar it as irrelevant, though he should be authorized to modify the stated areas of disagreement at the hearing if he feels it necessary to prevent prejudice. Cumulative or repetitious cross-examination may be more difficult to prevent. The hearing examiner should encourage participants to select a lead attorney or attorneys to conduct the whole examination. Further, the hearing examiner should consider establishing a reasonable time limitation for the completion of the examination. It may also be necessary to impose time restrictions on other participants with similar economic interests who desire to cross-examine the witness. Whether such steps are necessary is obviously a matter within the discretion of the hearing examiner presiding at the hearing.

To prevent "friendly" cross-examination, it may be appropriate to group participants by economic interest to determine who may examine witnesses called by other members of the group. In the *Foods for Special Dietary Uses* proceeding the hearing examiner folowed this procedure, treating all nongovernmental participants as having the same interest absent a showing to the contrary. On this basis the hearing examiner denied most requests to cross-examine witnesses presented by other parties. While some prejudice may have resulted (for example, the sugar producer's representative was not permitted to cross-examine witnesses presented by producers of artificial sweeteners), grouping participants for this purpose in some circumstances may be desirable.[125]

An ABA committee recommended that all witnesses should be presented "in a candid manner with cross-examination extending to the witnesses' entire field of competence," and that the scope of cross

125 Understandably, this type of proposal is anathema to many attorneys who feel that the right to ask questions is an inherent right of every attorney. They fear that other attorneys will be less effective or will not have precisely the same interests; also, client relations may be adversely affected if an attorney does not visibly participate in the proceeding. Voluntary cooperation by attorneys should be encouraged, but in extreme situations, as in *Foods for Special Dietary Uses*, the examiner may feel it necessary to impose substantial restrictions on cross-examination over the objection of attorneys.

should not be limited by the scope of direct. The latter portion of this recommendation was largely directed at incidents that occurred during the *Foods for Special Dietary Uses* hearing when counsel for the Government sought to restrict cross-examination of its witnesses to the scope of the direct testimony, thereby avoiding some potentially damaging testimony concerning the state of the nation's nutrition. The restriction sought by the Government was based on a principle applicable to adversary court proceedings and would seem to have little place in an administrative rulemaking proceeding. The government attorney's argument for restricting the scope of cross-examination was based on a narrow view of his role as an advocate rather than on the basis of whether the cross-examination would develop useful information. Because the FDA does not have subpoena power, an opponent, desiring to broaden the scope of the cross-examination, may have no other way of obtaining the desired testimony. Of course, such a broad-ranging cross-examination should be carefully controlled to eliminate purely cumulative or repetitious examination, and to avoid exceeding the area of the witness' competence. Before permitting such broadened cross-examination, the examiner should require the participant, first, to specify the areas he proposes to cover in the cross-examination, and secondly, to show that the proposed examination will produce material that cannot conveniently be introduced by direct testimony. This showing should ordinarily be made at the prehearing conference. If broadened cross-examination is permitted, the participant originally calling the witness should be permitted to cross-examine the witness regarding whatever testimony went beyond the scope of his direct examination.[126]

F. Discovery

Attorneys practicing before the FDA complain bitterly about the absence of effective discovery procedures. The FDA, however, has not expressed an interest in utilizing discovery techniques against private parties, and the absence of discovery apparently has not been a problem in the proceedings in which a private party is the proponent. The following discussion of the scope of discovery in section 701(e) proceedings is therefore directed solely to discovery against the agency.

In the past the FDA has often been reluctant to disclose the elements of its presentation before the hearing.[127] A particularly egregious

[126] The recommendation as approved appears in the Appendix, paragraph D.

[127] This relnctance sometimes has extended to the prehearing conference and even to the hearing itself. For example, in the *Peanut Butter* hearing the Government attorney

example of this reluctance occurred in the *Carbon Tetrachloride* hearing under the Federal Hazardous Substances Act. The attorney for one of the participants attempted to get the data on which the FDA was proposing to ban the use of carbon tetrachloride, in order to determine whether he would seek a full section 701(e) hearing. The FDA nevertheless declined to make available information in its files relating to several deaths caused by the use of carbon tetrachloride. The agency then issued the order and required that a hearing be held. The participant demanded that the information be made available pursuant to the Freedom of Information Act. The FDA again refused, on the ground that the information was protected by the physician-patient privilege. Litigation folowed, and in the ensuing appeal the Court of Appeals for the District of Columbia, in an opinion remanding the case to the district court, was unusually critical of the agency's response to this request.[128] A less grudging release of information prior to hearing might have avoided entirely the need for a formal hearing.[129]

The Administrative Conference has made extensive recommendations dealing with prehearing discovery in agency *adjudications*;[130] arguably such recommendations should also be applicable to section 701(e) proceedings. Rulemaking on a record, however, differs from typical agency adjudication in two important respects: first, the issues are usually considerably broader in rulemaking than in adjudication; and secondly, the issues have been substantially explored in the proposal-comment-order portion of the section 701(e) procedure. The danger of surprise is thus not as great as in normal adjudication. As a result, in rulemaking on a record the efforts of discovery should be directed to-

declined to provide in advance a description of the procedures followed by the FDA statisticians in preparing a study later to be introduced in evidence. In effect the Government attorney took the position that other participants may learn the nature of the Government's testimony only when it is actually presented orally at the hearing.

128 We are not impressed with this timing in terms of the Agency's responsiveness to the Congressional purposes evident in both the Freedom of Information Act and the statutory procedural scheme for rule making by the Agency embodied in the Federal Food, Drug, and Cosmetics Act . . . .

Ackerly v. Ley, 420 F.2d 1336, 1338 n.1 (D.C. Cir. 1969).

Again, however . . . we confess to a considerable lack of enthusiasm for the caliber of the Commissioner's performance in this seemingly erratic discharge of his responsibilities under the Freedom of Information Act. . . . This hardly comports with the vigorous defense of the two-stage device which the agency pressed—successfully—upon this court in Pharmaceutical Manufacturers Ass'n v. Gardner . . . . It is certainly not the kind of administrative performance envisaged by Congress in the Freedom of Information Act.

Id. at 1340. *See generally* Johnstone, *The Freedom of Information Act and the FDA*, 25 FOOD DRUG COSM. L.J. 296 (1970).

129 Heffron suggests, however, that the formal hearing in this proceeding was "intended to provide a test case for the FDA's powers and procedures in regard to banning in general, rather than a serious effort to prevail on the merits." H. HEFFRON, *supra* note 79, at 184.

130 Recommendation No. 21, approved June 2-3, 1970.

ward isolating issues and building a record rather than toward learning witnesses' versions of what happened. Any discovery procedures should be carefully tailored to the peculiar needs of the section 701(e) procedure.

1. Depositions.—Prehearing depositions appear undesirable in section 701(e) proceedings. Traditionally, the major problem in the hearings has been excessive cross-examination of expert witnesses presented by the agency. Probably the proposal to authorize depositions before the prehearing conference would merely transfer excessive examination to an earlier stage in the proceeding. Also, the agency has sometimes had difficulty obtaining the services of expert witnesses because of the likelihood of extensive cross-examination. The burden of being subjected to examination on depositions, as well as at the hearing, would probably increase the difficulty.

There may be some justification for permitting depositions of witnesses when their testimony relates to their activities rather than their opinions. Obtaining such testimony in written form at an early stage of the hearing, however, should be adequate in this situation.

2. Production of Prior Written Statements of Witnesses.—In the past, the FDA has sometimes declined to make available prior written statements of witnesses. In the *Foods for Special Dietary Uses* proceeding, the agency refused to produce several such statements and tapes of interviews on the ground that they were part of the development of the witnesses' direct testimony and thus immune from disclosure on an "attorney's work product" theory.[131] It seems reasonable to recognize such a privilege for two reasons. Most FDA witnesses are expert rather than material witnesses, and are unlikely to change their opinions on broad policy questions in the course of reducing their views to question-and-answer form. Cross-examination of these witnesses on the basis of minor variations in language between original statements and subsequent testimony appears unproductive compared to cases in which the witness' recollection of prior events is critical. Also, as a practical matter, to require routine disclosure of these statements and tapes may simply cause government attorneys to develop the direct testimony of their witnesses in different ways.

Production of statements unrelated to the preparation of testimony is an entirely different matter. In the past, the FDA has been less than generous in making such statements available prior to the hearing. This

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[131] *See* Hickman v. Taylor, 329 U.S. 495 (1947).

attitude is undesirable and does not lead to the development of a complete and accurate record.[132] The FDA should routinely make available to any participant prior statements of a witness that are in its files if the statements relate to the subject matter of the expected testimony, and were made before the person agreed to become a witness for the agency. If the witness is an agency employee, requests for prior statements should be treated as requests for production of documents and be subject to the appropriate restrictions on documents.[133] "Statements," as used here, should include only written statements signed or adopted by a witness, or a recording or transcription of an oral statement made by the witness.

The FDA should also make available any of its witnesses' published statements or books it may have, if they relate to the subject matter of the expected testimony. Whether statements produced by a witness or by the agency may be introduced into evidence or used as the basis of cross-examination should be determined by the recommendation dealing with relevancy and the scope of permissible cross-examination.

3. Interrogatories and Requests for Admissions.—Present FDA regulations do not provide for the use of either written interrogatories or requests for admissions. These devices might be marginally useful in isolating the factual areas in dispute or in enabling participants to prepare for the formal hearing. On the other hand, formulating responses to a large number of interrogatories or requests for admissions, often phrased in different language by different participants, might impose a substantial burden on the agency's legal staff. On balance, the revised prehearing conference procedure—particularly the agency's statement of position and the distribution of the Government's written direct testimony in advance of the hearing itself—should provide sufficient advance information about the Government's case to render the use of either of these discovery techniques unnecessary.

4. Production of Documents and Tangible Things.—A participant in a section 701(e) proceeding, requesting the agency to produce documents or other tangible objects, may be legally entitled to them under the Freedom of Information Act. The FDA, however, has tended to construe the Act's exceptions broadly. Apparently the agency gener-

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132 The ABA committee recommended that, when requested by any party, all witnesses should produce for inspection and use by the parties the relevant portions of prior written statements made by the witness as well as other documentary material specifically relied upon by the witness, and that appropriate safeguards be provided to protect trade secrets and privileged communications. I substantially agree with these recommendations.

133 For a discussion of these restrictions see text accompanying note 137 *infra*.

ally refuses to disclose unless it is legally compelled to do so. As a consequence, the FDA has refused to disclose obviously relevant information involved in a pending section 701(e) proceeding.[134] Within the last two years, for example, it has declined to release: (1) a report by the National Bureau of Standards on the safety of toy lawnmowers; (2) toxicology studies on food additives and drugs; (3) reports of factory inspections; and (4) expressions of opinion by investigators and outside expert consultants.

The Freedom of Information Act probably requires the FDA to release otherwise exempt material that forms the basis of its proposed rulemaking.[135] The agency, however, should not wait for the prod of the courts, but should routinely make available to parties all unprivileged information in its files relating to the matters at issue. Documents that contain factual information should usually be made available upon request. The FDA should proceed on the assumption that disclosure is presumptively required in every case, and that refusal to release a document must be based on strong reasons. A desirable test might be to allow withholding if the requested document or information clearly falls within an area of privilege *and* if disclosure would clearly harm third persons or seriously interfere with agency operations. The suggested approach would require a complete change in the agency's attitude on disclosure.

Most problems of disclosure faced by the agency fall into three areas: first, trade secrets or confidential research, development, or commercial information relating to persons or parties other than the Government; secondly, internal information (e.g., statements, correspondence, or memoranda) relating to violations of law by third-party nonparticipants in the hearing or enforcement proceedings against alleged violators; and finally, internal memoranda or letters, the disclosure of which arguably may inhibit frank written dialogue in the process of the agency's formulation of a legal or policy position. Preliminary drafts, alternatives, comments on proposed opinions, and the like usually should not be disclosed.[136]

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134 See, for example, the discussion of the carbon tetrachloride hearing, text accompanying notes 128-29 *supra*. Another incident occurred during the *Foods for Special Dietary Uses* hearing. Attorneys requested the release of memoranda prepared by the FDA for their immediate superior relating to suggested improvements in hearing procedures. The release of these documents was requested on May 1, 1969. On November 16, 1970, the FDA finally released the documents, commenting that, while the documents were privileged under the intra-agency memorandum exception, the agency felt it inappropriate to invoke the privilege since "they have been circulated and discussed freely, both within and without the agency." Whatever the legal status of these documents under the Freedom of Information Act, they should have been released after action had been taken on them.

135 Ackerly v. Ley, 420 F.2d 1336 (D.C. Cir. 1969).

136 An attorney, commenting on this sentence, has posed the policy conflict sharply:

Even when the agency concludes that disclosure should not be made under the foregoing test, it should consider whether the consent of other persons may be obtained that would permit release of the information, or whether a summary or digest of the requested document may be made that makes the essence of the information available to the participant.

5. Control over Discovery.—Ultimately the agency must determine the scope and extent of permitted discovery, particularly in the sensitive area of production of documents and prior statements of witnesses. If discovery is to be meaningful, the agency must devise an expeditious procedure to resolve questions that may arise as to the scope of discovery; these questions should be resolved in days, not weeks or months.

Requests for information under the Freedom of Information Act are handled by the Information Office of HEW. When discovery is sought in connection with a pending hearing, it seems preferable to have the request considered in the first instance by the hearing examiner who is to preside at the hearing. His decision should be subject to a right of interlocutory appeal to the agency. The hearing examiner should also be vested with authority to issue protective orders, designed to protect the interest of any person or participant.[137]

> I personally disagree with your position concerning nondisclosure of internal memoranda or letters, although I recognize there is support for it in the text and legislative history of the Freedom of Information Act. To illustrate my viewpoint, if a qualified FDA Bureau Chief has substantial doubts about the scientific basis for a particular action, I should think that opponents of this action should be entitled to get this fact into the record for the benefit of the Commissioner who may ultimately make the decision and of reviewing courts. Since FDA attorneys will presumably not introduce testimony hostile to the regulations ultimately put at issue, and since such officials are not now subject to subpoena, disclosure of their memoranda may be the only effective way to disclose the true facts. In any event, if your comment . . . implies that all such documents are entitled to any greater protection than they are given by the Freedom of Information Act, I believe it is incorrect.

Letter from James M. Johnstone to Robert W. Hamilton, Jan. 11, 1971. *See also* Johnstone, *supra* note 128. If the Bureau Chief memorandum described by Mr. Johnstone were subject to discovery, it is probable that subsequent intra-agency controversies of this nature would be resolved orally or informally. There is no reason for such controversies to be the subject of an externalized adversary process. The agency itself should have internal procedures by which such conflicting views are forwarded to the administrator for final determination. Implicit in Mr. Johnstone's statement is the fear that high-level administrators within the FDA may make a decision without knowing of or evaluating the Bureau Chief's views. There may be some reason for such apprehensions because instances have occurred when memoranda from technical personnel within the FDA have been edited by FDA administrators or have not been forwarded at all. Several such incidents, one occurring as late as early 1969, were the subject of a hearing before the Fountain Committee in 1970. *Hearing Before the Subcommittee on Intergovernmental Relations of the House Comm. on Gov't Operations*, 91st Cong., 2d Sess., at 21-22, 102-31 (1970). *See also* TURNER, supra note 4, at 13-14, 191-95.

137 The recommendation as approved appears in the Appendix, paragraph E.

G. Ex Parte *Communications*

The ABA committee recommended the publication of a regulation which would make it clear that, after the announcement in the *Federal Register* of a definite date for a hearing, all *ex parte* communications to employees of HEW or the FDA concerning the issues raised during the hearing would be made a part of the public record. Several events that occurred during the *Foods for Special Dietary Uses* proceeding fostered this proposal. I am in substantial agreement with this recommendation. The FDA has promulgated the following regulation relating to *ex parte* contacts that roughly parallels the ABA proposal:

> If any official of the Food and Drug Administration is contacted by any individual in private or public life concerning any matter which is the subject of a public hearing, the official who is contacted shall prepare a memorandum setting forth the substance of the conversation and shall file this memorandum in the appropriate public docket file.[138]

Even this rather modest provision appears to have been largely ignored by the FDA prior to the *Foods for Special Dietary Uses* proceeding.[139]

Naturally there is extensive contact between agency personnel and industry representatives at the FDA during the early stages of FDA decisionmaking. Applications are sometimes "walked through" the agency; former FDA employees find ready employment in industry in part because of their knowledge of FDA practices, personnel, and policies. Inquiries concerning status, submissions of additional data, and conferences with low and high level agency personnel are common. A public hearing, however, is scheduled only after a very extensive information rulemaking procedure during which possibilities of negotiation and compromise are investigated. Therefore, *ex parte* contacts of the *Sangamon Valley*[140] type are unlikely to occur. This certainly was the case in the *Foods for Special Dietary Uses* proceeding, where the "section 2.104 file" reveals no contacts of the *Sangamon Valley* type at all.[141]

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138 21 C.F.R. § 2.104 (1971).

139 The hearing clerk cannot recall any memorandum being filed pursuant to § 2.104 prior to that proceeding. A special "section 2.104 file" was created for that proceeding.

140 *Sangamon Valley Television Corp. v. United States*, 269 F.2d 221 (D.C. Cir. 1959), *remanded for new proceedings*, 294 F.2d 742 (D.C. Cir. 1961).

141 The file contains memoranda dealing with several incidents.

On or about October 31, 1968, Commissioner Ley and Associate Commissioner Kirk met with the chairmen of the Food and Nutrition Board of the National Academy of Sciences and the AMA's Council on Food and Nutrition to discuss the *Foods for Special Dietary Uses* proceeding and the proposed regulations. At that time the formal hearing was in process. The memorandum describing this meeting (which was not placed in the § 2.104 file until September 19, 1969) concludes with the following:

> The meeting closed with a strong invitation to both [chairmen] that their groups

The hearing examiner in *Foods for Special Dietary Uses* filed several memoranda in the section 2.104 file. The most serious incidents involved three meetings between the hearing examiner, the FDA commissioner, and other FDA officials. These meetings were devoted to the procedural aspects of the hearing, and were designed to expedite the hearing. The attorneys actually representing the FDA at the hearing did not participate in these meetings, although memoranda prepared by them served as the bases of suggestions for improving the proceeding. The hearing examiner filed memoranda describing each of these meetings in the section 2.104 file, but the agency declined to make public the memoranda until long after the hearings were concluded.

The three meetings did not relate to substantive issues at the hearing. Besides these three meetings, there appear to have been no substantial off the record *ex parte* contacts between the FDA hearing examiners and other persons within or without the agency.[142] The hearing examiners are directly subordinate to the Commissioner, but they work in virtual isolation, without technical, accounting, or legal assistance. Their offices are physically separate from the offices of both attorneys and technical staff of the FDA. The attorneys who actually conduct the

submit to the Commissioner any views that they have about the pending regulations scheduled to be covered by the Hearings. Where the advisory groups disagree with the figures or statements in the regulations, the Commissioner would be most happy to have their views as to how the regulations should be set up and the reasons therefor.

This is a perplexing incident. The persons discussing the merits of the regulations with the Commissioner had no direct economic interest in the proceeding. The issues involved in the discussion involved broad questions of policy, not requests for special or favorable treatment. Clearly, this is not the kind of contact that gave rise to so much concern during the early 1960's, leading to a recommendation by the temporary Administrative Conference. Recommendation No. 16, approved June 29, 1962, printed in SELECTED REPORTS OF THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, S. DOC. No. 24, 88th Cong., 1st Sess. (1963), and the adoption of detailed regulations dealing with *ex parte* contacts by many agencies. *See* REPORT OF THE SUBCOMM. ON EX PARTE COMMUNICATIONS, 3 ABA ADMINISTRATIVE LAW SECTION 4 (1966). The leading article on the subject is Peck, *Regulation and Control of Ex Parte Communications with Administrative Agencies*, 76 HARV. L. REV. 233 (1962). Nevertheless it is difficult to square obtaining information of this nature on an off-the-record basis with the notion that the formal record constitutes "the exclusive record for decision."

This incident probably reflects poor staff work at an earlier stage of the proceeding. Information of the type requested should have been obtained by the agency from the AMA and NAS during the formulation of the proposal or in connection with preparation of the hearings, not during the formal hearing.

The § 2.104 file also contains several letters from doctors and others relating to the FDA's position in this hearing. These writers also appeared to have no economic interest in the proceeding.

142 One other *ex parte* contact between the hearing examiner and a participant, in retrospect, is rather amusing. A consumer participant in the *Foods for Special Dietary Uses* proceeding tried to borrow the hearing examiner's copy of the daily transcript on a Saturday morning when the hearing clerk's office was closed. He was apparently directed in no uncertain terms to leave the immediate premises.

The hearing examiners also have received, from time to time, calls or inquiries about the status or schedule for hearings.

hearing are in the office of the General Counsel of HEW, and there appears to be some coolness between the individual members of this staff and the hearing examiners.[143]

The basic problems with the present section 2.104 do not concern the concept of disclosure of *ex parte* communications as giving sufficient protection, but relate to the uncertainty as to when such disclosure is required under the section. As one attorney commented, the real problem is that the FDA has not defined which types of *ex parte* contacts are proper and which are not.

> The present situation is that FDA has an ex parte contact rule which sets up no standards governing such contacts and at the same time requires disclosure under terms which would be ridiculous if complied with literally. The requirement for disclosure is given a grudging interpretation both by the Assistant General Counsel's office and by FDA officials. This is certainly at least one of the causes of the high degree of mistrust which exists between the private bar and the Assistant General Counsel's office.[144]

An amendment of section 2.104 seems desirable. The amended rule should specify the persons covered by the *ex parte* contact rule, the period the rule is in effect, the types of communication covered, and the type of disclosure required. Participants should be permitted to controvert information obtained in violation of the section. Finally, persons covered by the rule should refrain from soliciting *ex parte* contacts.[145]

H. Separation of Functions in the Decisional Process

Legal matters relating to foods and drugs and the actual conduct of section 701(e) hearings are handled by the Food, Drug and Environmental Health Division of the Office of General Counsel of HEW.[146] Traditionally, this office has not followed a policy of separation of functions. As the office has fewer than 20 attorneys, each attorney has handled a variety of problems as they arise, and the one acquainted with a given proceeding has usually participated in all stages of that proceeding. Thus the attorney who conducts the hearing may also participate

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143 The hearing examiner *ex parte* contacts that occurred in connection with the *Foods for Special Dietary Uses* hearing are unlikely to recur. They arose because of the unfortunate circumstances surrounding that hearing.

144 Letter from James E. Johnstone, *supra* note 136.

145 The recommendation as approved appears in the Appendix, paragraph F.

146 The office providing legal counsel for the FDA is not itself part of the FDA, but of the FDA's parent agency, HEW. In practice, however, the administrative structure has operated smoothly. As is often the case, the strength of personalities rather than the formal administrative structure has determined the effectiveness of the administrative operation

actively in reviewing the hearing examiner's report and preparing the Commissioner's tentative and final decisions.[147] Several FDA hearing attorneys have commented that, after presenting the FDA's case at the hearing, they feel their direct participation in the decisionmaking process is undesirable or improper, and have attempted to limit or minimize their participation. At the *Foods for Special Dietary Uses* proceeding, one attorney gave assurances that he would not personally participate in formulating the final decision, and he has attempted to avoid doing so.

Given the strong adversary nature of many of the FDA's hearings, the present practice creates an impression of unfairness and is plainly undesirable.[148] At the very least, the attorney who conducts the hearing and prepares proposed findings of fact and conclusions of law for presentation to the examiner should not be directly involved in the formulation of the tentative or final decision. At a minimum, this function should be placed in the hands of attorneys who have not participated in the hearing.

The more difficult question is whether to go one step farther and require a complete separation of functions.[149] Even if the hearing attorney is eliminated from the decisional process, his superior, the Assis-

147 The attorney involved abruptly changes hats with the submission of the hearing examiner's report. This report is not made available to the "participants" at the hearing, and of course the FDA trial attorney, as a participant, does not receive this report, which is sent directly to the Commissioner's office. However, the report is then routed directly to him by the Commissioner's office for purposes of review and comment.

148 Considerations of policy and fairness rather than strict legal requirements control since it seems clear that the strict separation of functions that the APA requires in adjudicatory proceedings is not applicable to § 701(e) proceedings. The APA only makes §§ 7 and 8 applicable to rulemaking on a record, not § 5(c), which requires separation of functions. In the leading case of Willapoint Oysters v. Ewing, 174 F.2d 676 (9th Cir.), *cert. denied*, 338 U.S. 860 (1949), the court upheld the exclusion of evidence that the chief Government witness and Government counsel aided in and prepared portions of the Commissioner's findings. The court held § 5(c) of the APA inapplicable because the proceeding involved "rulemaking" rather than "adjudication." Further, there was no violation of the participant's constitutional right to a hearing, and the applicable statutes providing for a hearing did not specify any particular procedure. There has been one *dubitante* expressed about the *Willapoint* holding. Levine, *Separation of Functions in FDA Administrative Proceedings*, 23 FOOD DRUG COSM. L.J. 132 (1968). The author points out that serious question exists about the propriety of the FDA procedures in essentially adjudicatory proceedings, such as a proceeding to withdraw a New Drug Application. The author cites one unreported decision, invalidating such a proceeding for violation of § 5(c) of the APA. Food standards and the other § 701(e) proceedings, however, do not appear to be subject to § 5(c).

149 The ABA has recommended a complete separation of functions, and even more drastic suggestions have been made. It has been suggested that the hearing examiners should be moved out of the FDA and be made a part of HEW, where presumably they would exercise greater independence. Pendergast, *The Challenge to Improve the Food and Drug Administration*, *supra* note 100. It has also been suggested that the decisionmaking function should be placed in the hands of the Secretary of HEW rather than the Commissioner of the FDA. Klienfield, *supra* note 103. These latter suggestions appear to be extreme.

tant General Counsel, will exercise supervision and control over the hearing attorney and over the attorney who reviews the hearing examiner's report, digests the record, and prepares drafts of tentative and final decisions. Furthermore, the Assistant General Counsel will actively advise and assist the Commissioner in making the decision; at an earlier stage he probably also participated in the original decision to propose the rule and in other steps of the process.

To require a complete separation of functions would impose a serious strain on the current resources of the agency. The small number of proceedings and the small legal staff make a complete separation of functions a luxury that the agency should forego at the present time, if it can. Further, I am not persuaded that a complete separation is essential for basic fairness. In the past, the Assistant General Counsel has not exercised close, day-to-day supervision over the trial attorneys. His control has been general in character, and he has not actively participated in recent hearings. To a considerable extent, he is not affected by the partisan, adversary, and often acrimonious give-and-take that occurs during a controverted hearing.

HEW should make internal staff changes to broaden the separation between the attorneys who conduct formal hearings and those who assist the Commissioner in the decisionmaking process. While the problem appears to be acute only with respect to the Office of General Counsel, the same principles should be applicable to FDA technical and enforcement personnel who help prepare the FDA's presentation at the hearing.[150]

I. Participation of Consumer Groups and Persons Not Represented by Counsel

Section 701(e) provides that "any interested person" may be heard at the hearing in person or by representatives. The regulations require

150 The Food, Drug and Environmental Health Division of the Office of General Counsel is currently in a state of flux. From 1939 until the fall of 1971, this office was headed by one man who was the acknowledged legal expert in Government on the Food, Drug and Cosmetic Act. His personality and views have had a tremendous impact on the entire rulemaking process, and indeed on the substance of the rules themselves. His successor, who took office Sept. 1, 1971, was formerly an attorney with a leading Washington, D.C., law firm with an extensive food and drug practice. The new Assistant General Counsel is in his thirties.

In addition to this change in top legal personnel, a sectioning of this office into three units—tentatively designated Administrative Regulation, Trials, and Appeals—has recently been approved though not yet implemented. The creation of sections may tend of its own momentum to cause a separation of functions to take place within this office, though the original justification for the sectioning was to improve the salaries of staff members.

It is probable that ultimately the FDA will be forced to adopt a complete separation of functions organization for proceedings of an adjudicatory nature. If so, it would be desirable to conduct § 701(e) proceedings on a complete separation of functions basis also. The recommendation as approved appears in the Appendix, paragraph G.

that a written appearance be filed and that the "interest" of the person be described with particularity, but do not define what constitutes a suitable interest.[151] Presumably consumer groups have the requisite interest. Indeed, there may be nothing to prevent a suburban Rockville housewife from filing a notice of appearance and thereafter personally cross-examining the Government's expert witnesses. Such lay witnesses are not unknown. In the *Peanut Butter* hearing, a representative of a federation of housewives actively participated in the hearing. The same person also appeared in the *Foods for Special Dietary Uses* proceeding, as did a physician without prior legal training.

The impact of these lay consumer representatives has been marginal. Usually they are inexperienced in the skills of cross-examination and unaware of legal limitations on questions that may be asked. They are usually unable to purchase a copy of the daily transcript, and hence have only a general notion of what the witness actually said on direct examination.[152] As a result, their questioning of witnesses tends to be time-consuming and unproductive. Further, their position at the hearing is difficult and ambiguous. They are not lawyers but are participating in a proceeding that has many of the attributes of a trial. Other participants are represented by highly skilled attorneys who tolerate—barely—the lay intrusion into the lawyer's domain. Views expressed by these persons may be summarily dismissed on the ground that they do not "really" represent the general consumer, but rather some interest group. In private, they may be referred to in a derogatory fashion. In many instances, these persons would be more comfortable as witnesses than as attorneys, because essentially they are attempting to express a point of view they feel would otherwise not be heard.

Obviously, it would be desirable to limit participation in the formal hearing to persons who are attorneys or who are represented by counsel. Whether it is legal to do so under section 701(e) is doubtful. The statutory provision that any interested person may be "heard in person or by representative" arguably may be satisfied by giving such a person an opportunity to present his views on the record, perhaps at the beginning of the hearing. The more logical construction suggests

151 21 C.F.R. §§ 2.58-.64 (1971). The hearing examiner is authorized to exclude from the hearing persons engaged in "disrespectful, disorderly, or contumacious language or contemptuous conduct, . . . refusal to adhere to reasonable standards of orderly and ethical conduct, at any hearing." *Id.* § 2.62.

152 In the *Foods for Special Dietary Uses* proceeding, the FDA received five copies of the daily transcript. For much of the proceeding, four copies were used internally and one copy was placed in the hearing clerk's office for the use of the press and public. During the latter part of the hearing, two copies were available in the hearing clerk's office. Of course, the routine use of written direct testimony will alleviate this problem of access to the transcript.

that a person may participate in all aspects of the hearing "in person or by representative," or that the concept of being heard includes a right to ask questions. In any event, the agency should encourage such persons to participate in the comment stage of the proceeding, and then, if they wish to state their views for the formal record, to limit their appearance to a narrative statement given at some convenient point in the hearing. This appearance should be permitted even though the person is not called as a witness by a participant.

These lay participants aside, section 701(e) hearings in the past have largely developed into a contest between agency and industry attorneys. Theoretically, the agency represents the public interest. Because of the nature of the section 701(e) proceeding, however, the agency attorneys actually seek to build a record that will contain factual evidence to support decisions already made by the agency. Despite protestations to the contrary, agency attorneys are not actually engaging in a fact-finding excursion with the chips falling where they may. As a result, neither the agency nor the industry may desire to explore certain areas of testimony if they independently conclude that the testimony may not support their position. A consumer representative represented by counsel and not committed to the agency viewpoint might produce nonpartisan testimony.

Certainly the consumer should be represented forcefully at earlier stages of the section 701(e) proceeding. At the proposal stage, for example, consumer representation clearly can be helpful because the agency presumably is still considering possible alternatives. At the hearing stage, however, the alternative has been selected, and the agency is seeking to justify its choice. The desirability of forceful consumer participation at this stage is considerably less clear. Indeed, the agency has sometimes been reluctant to hold hearings when extensive consumer participation appeared likely. Still, consumer participation should be encouraged at the formal hearing stage for two reasons. First, the information developed by consumer groups may not have been previously available to the agency. Some indication of this appears in the *Foods for Special Dietary Uses* transcript, and it is probable that forceful representation of a different point of view would increase the amount of new relevant information in the record. Secondly, participation by consumer groups may permit the agency attorney to take a more judicious, less adversary stance at the hearing, and the agency itself may be given a broader middle ground on which to take a stand.

In future hearings of importance specific consumer groups may be

able to retain attorneys or may be represented by so-called public interest law firms. The Public Interest Research Group, formed by Ralph Nader, may be interested in future section 701(e) proceedings, along with other possible consumer representatives. The Administrative Conference has proposed a "people's counsel" to participate in rulemaking proceedings. A consumer's representative has been created by executive order and legislation is pending in Congress to formalize and fund this position. The viewpoint of these organizations may also be useful in building the section 701(e) record.[153]

J. Administrative Control over the Decision To Hold a Hearing

Section 701(e) grants the right to a formal hearing to any person "adversely affected" by the proposed rulemaking.[154] The regulations add the requirement that a request for a hearing state "reasonable grounds which, if true, are adequate to justify the relief sought."[155] Despite these apparently absolute provisions, the FDA has developed the practice of exercising a limited degree of discretion in the decision whether to hold a hearing, and in some instances has denied a hearing even though there appeared to be substantial factual disputes.

If a formal hearing is denied even though a person has requested one, rulemaking on a record terminates at the conclusion of the proposal-comment-order stage, in much the same manner as noncontroverted FDA rulemaking or a typical rulemaking procedure in other agencies. As an abstract matter, much may be said for encouraging this practice. Yet it may involve the denial of a right specifically granted by statute and may affect the scope of available judicial review.

Granting or denying a formal hearing also has some of the attributes of a summary judgment. The Administrative Conference has recommended that agencies adopt summary judgment procedures in "adjudicatory *or rulemaking* proceeding[s] required by statute to be determined on the record."[156] Such a judgment may be granted if "the pleadings, affidavits, materials obtained by discovery or otherwise, or matters officially noticed, show that there is no genuine issue as to any material fact." The differences between what the FDA does in denying

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153 The recommendation as approved appears in the Appendix, paragraph H.

154 21 U.S.C. § 371(e)(2) (1970).

155 21 C.F.R. § 2.67(b)(5) (1971). The Federal Trade Commission regulations under the Fair Packaging and Labeling Act, 15 U.S.C. § 1455 (1970), are even more stringent. They grant a hearing only if the objections are "supported by reasonable grounds that, if valid and factually supported, may be adequate to justify the relief sought." 16 C.F.R. § 1.16(g) (1971).

156 Approved June 2-3, 1970.

a hearing and what the Conference proposes, however, are fundamental in two respects: first, the Conference proposal assumes a judgment made on the basis of formal documents that may be reviewed by the agency itself and by courts on judicial review, while the practice followed by the FDA results in the creation of no formal record on which the denial of a hearing or the substantive decision itself may be reviewed; and secondly, the Conference proposal contemplates a summary judgment only when there is no genuine issue of fact, whereas the FDA procedures may result in denial of a hearing even in the face of genuine factual controversies.

The starting point for the development of the FDA's rather novel denial of hearing practice is a series of cases and rulings involving coal tar colors. In *Dyestuffs and Chemicals, Inc. v. Fleming*,[157] the Commissioner ordered four coal tar colors removed from the approved list of color additives. An objection and request for hearing was filed primarily on the ground that the evidence of potential injury relied upon by the FDA was based on animal tests and involved amounts far in excess of the actual level of use in the human diet. Other objections stated that the reasonably anticipated uses of the four colors would not justify any fear of injury, and that the Commissioner should prohibit excessive concentrations rather than barring the "proper and harmless use" now being made of the colors. After these objections were filed, the Supreme Court, in an unrelated case,[158] construed the color additive section to mean that "where a coal-tar color is not harmless, it is not to be certified," and that the FDA therefore lacked power to permit the use of harmful colors through a system of tolerances.

After this decision, the Administrator published an order refusing to hold a hearing on the ground that the Supreme Court had established the proper construction of the law, and that the objections filed were thus "without substance, and no purpose could be served by holding a public hearing." The court of appeals agreed that the objections filed were "legally insufficient," and therefore a hearing need not be held.[159] Professor Davis has criticized this decision on the ground that there is a "dangerous potentiality" in not respecting the statutory requirement of a hearing when substantial issues are presented.[160] Subsequent developments have lent credence to his warning.

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157 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960).

158 Flemming v. Florida Citrus Exchange, 358 U.S. 153 (1958).

159 271 F.2d 281, 286 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960).

160 K. DAVIS, *supra* note 57, § 6.05 (1965 Supp.). In his 1970 Supplement, Davis adds, "The Dyestuffs case probably stands as authority approving the denial of a hearing, even when a hearing is required by statute, on objections an administrator deems legally insufficient, even when the issues of legal sufficiency are live and difficult." *Id.*, § 6.05 (1970 Supp.).

Following the *Dyestuffs and Chemicals* decision, several other issues relating to the right to a hearing arose in connection with the delisting of coal tar colors. In a proceeding involving different colors, the FDA held a hearing on whether certain animal tests performed by the FDA "were properly planned and executed," and whether tests on certain colors permitted the delisting of other colors because of the chemical relationship between the colors.[161] On the other hand, when the Commissioner sought to withdraw his certificate of harmlessness on specific *batches* of coal tar colors on the ground that the color itself had been delisted after the batch certificate was issued, the FDA declined to grant a hearing. The agency ruled that since the Department's construction of the statute was settled, and since the objection was to the interpretation of the statute, the question was "not one on which a hearing would contribute to a solution," but one that could only be resolved by the courts.[162]

On review, the court upheld the Commissioner's position that he had authority to revoke batch certificates after he had delisted the colors.[163] The court, however, rejected the FDA's position in connection with a color known as Red No. 1. The commissioner had not specifically found that this color was harmful, but had merely amended the specifications relating to the color after the specific batches were certified. The court ruled that nothing in the record indicated that Red No. 1 was harmful, a question of fact. Noting that no underlying factual determination "of a sort sufficient to justify withdrawal of certificates" had been made, the court held that the objections raised more than a "legal issue" and forbade the summary withdrawal of certification without a more explicit finding.[164]

Acting pursuant to the authority granted in the *Dyestuffs and Chemicals* case, the agency has denied formal hearings in a variety of different situations. These situations may be roughly classified in three categories: (1) cases presenting purely legal questions; (2) cases involving noncontrolling factual issues; and (3) cases in which the FDA simply feels a hearing would serve no purpose.

1. Legal Questions.—The FDA has often refused to hold formal hearings when only legal questions were involved, claiming that there were no factual issues on which to hold a hearing. For example, the FDA recently refused to hold a hearing over whether open, multi-unit convenience containers for soft drinks constituted "packages" under

161 25 Fed. Reg. 903 (1960).
162 *Id.* at 143.
163 Certified Color Indus. Comm. v. HEW, 283 F.2d 622 (2d Cir. 1960).
164 *Id.* at 628.

the Fair Packaging and Labeling Act.[165] Similarly, the FDA refused to hold a hearing over whether Congress had authority to include hallucinogenic drugs such as LSD under the control provisions of the Drug Abuse Control Act of 1965, or whether that act authorized the Commissioner to impose the drug inventory requirements he was proposing.[166] An objection to the requirement imposed under the Fair Packaging and Labeling Act that the corporate name of the manufacturer, packer or distributor appear on every label (even when a division of the corporation was designated) was similarly rejected on the ground that it presented solely a question of law.[167]

2. *Noncontrolling Factual Issues.*—The FDA has also refused to hold hearings when objections have raised factual issues, but it appears unlikely that the resolution of the factual issues would affect the rule under consideration. For example, in the *DSS in Cocoa* proceeding, the agency rejected objections that DSS-treated cocoa was undesirable because it was possible that through manufacturing errors customers might receive unlabeled DSS-treated cocoa, and that permitting DSS would require the use of flammable solvents that increase hazards in the production area. The agency rejected these objections on the theory that it is the duty of manufacturers generally to maintain identity of raw materials and provide precautions against industrial safety hazards. In the same proceeding, another objection stated that DSS should not be permitted in cocoa because it might cause bitterness when the maximum permissible level of DSS is approached. The agency rejected this objection as a ground for a hearing, claiming that bitterness is not always encountered under such conditions, and that in any event the bitterness often appears to be attributable to the natural bitterness of cocoa as much as to the additive.[168] This is obviously a summary resolution of a factual issue, though it is arguable whether the opposite resolution would have affected the outcome of the proceeding. The difference, however, between this rejected issue and the issue on which the hearing was actually held—"Whether dioctyl sodium sulfosuccinate would

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165 35 Fed. Reg. 8550 (1970).

166 31 *id.* at 7174 (1966).

167 32 *id.* at 13277 (1967). On the other hand, in the *Prescription Drug Advertising* proceeding, the FDA set a hearing on certain purely legal issues, whether proposed regulations exceeded the agency's authority or were otherwise invalid. The order explains:
"The Department believes these are legal issues of statutory interpretation which must ultimately be settled by the Courts, but the hearing will offer the opportunity to present evidence on any factual matter relating to the issues." 28 *id.* at 9837-38 (1963). The hearing was actually held; basically it contributed little except to initiate informal discussions between the drug industry and FDA on the scope of the regulations.

168 34 *id.* at 19140 (1969).

accomplish its intended effect to rapidly disperse cocoa in dry beverage bases when mixed with water or milk"—is not readily apparent.

3. Cases in Which the FDA Feels a Hearing Would Serve No Purpose.—The FDA has sometimes refused to grant a hearing when the statute seems clearly and unambiguously to create a right to a formal hearing. These are the most troublesome cases. In considering the proposed regulations under the Fair Packaging and Labeling Act, for example, several objections were raised to the requirement that the statement of net quantity of contents be placed on the lower 30 percent of the label, and that such information be displayed in type of stated sizes. Many of these objections sought to put the FDA to its proof, and alleged that the proposals were not supported by substantial evidence. While it is clear that these issues involve policy questions on which a formal evidentiary hearing would probably provide little assistance, section 701(e) seems to require a hearing. Faced with considerable pressure to promulgate the regulations promptly, however, the agency denied the objectors a hearing. "Since the statute provides that the selection of the uniform location shall be made by the Commissioner and not by popular vote, and since no substantial objection to his location has been offered," the agency wrote, "there is no basis for a public hearing."[169] Objections relating to the type size were rejected on the same basis.

In the proceeding relating to fireworks under the Federal Hazardous Substances Act, the National Society for the Prevention of Blindness objected to a proposed rule, and requested a hearing on the following grounds: (1) the regulation was too narrow in that it did not ban all fireworks: (2) the labeling of all fireworks would not adequately protect purchasers; and (3) the three-year record-keeping requirement should be increased to ten years. The agency denied the request for a hearing and ordered the rule to become effective immediately. It stated that "the objector is not opposed to the order as written, but rather is requesting that the scope of the order be expanded."[170] The objection, however, was treated as a petition to ban all fireworks and a new proceeding was instituted. In this instance, the agency was again under some pressure to act expeditiously before the Fourth of July holiday, and the solution it adopted appears sensible.

In the *Whole Fish Protein Concentrate* proceeding, numerous

[169] 32 *id.* at 13276-77 (1967). The position taken by the FDA in this ruling is vigorously contested by Forte, *supra* note 16. Mr. Forte represented one of the participants in the proceeding and clearly would have relished a court review of the Commissioner's position.

[170] 35 *id.* at 1045 (1970).

consumer and nonmanufacturing groups objected to the proposal to permit the marketing of a food supplement made from whole hake. Many objections went to the safety and purity of the product, as well as to the desirability of permitting such a product in the American diet—issues on which a hearing would normally have been held. The agency nevertheless denied all requests for a hearing, saying only that "these objections and requests for a hearing are not supported by grounds legally sufficient to justify the relief sought."[171] It is perhaps noteworthy that in this proceeding no one with a commercial interest requested a hearing; the request of the American Dry Milk Institute was withdrawn shortly before all other requests for a hearing were denied.

In the *Optional Use of Direct Acidification Method of Manufacture of Cottage Cheese* proceeding, a manufacturer of traditional cottage cheese asked for a hearing on whether the proposed labeling of "direct acidification" cottage cheese was misleading. He asserted that a random survey of twenty consumers indicated that they did not understand the meaning of the proposed label. The Commissioner concluded that the objection was "without sufficient support to merit a stay of the order and the granting of a public hearing."[172] Abstractly, it would seem that the objector had in fact stated a sufficient issue to justify a hearing. Again, however, it is unlikely that the issue would be deemed of sufficient economic importance to justify judicial review.

The issues on which hearings were denied in most of these proceedings, such as the location of required information on a label or the desirability of permitting the sale of a type of fish flour, are probably not ones on which an evidentiary hearing would provide much assistance. The choices involved economic or policy decisions and the relevant factual information could easily be obtained without a formal hearing. The issues, however, appear to be indistinguishable in principle from the question, for example, whether "peanut butter" should be a product consisting of 90 percent or 87 percent peanuts. Similarly, Professor Davis has vigorously criticized section 701(e) on the ground that it requires the agency to hold hearings on questions such as whether "golden" should be a synonym for "yellow" in canned corn, or whether pear halves should weigh a minimum of three-fifths or four-fifths of an ounce.[173] Such questions also appear indistinguishable in principle from the issues on which hearings were refused in these proceedings.

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171 33 *id.* at 40983 (1968).
172 36 *id.* at 7421 (1971).
173 1 K. DAVIS, *supra* note 57, § 606.

The number of examples in this category are relatively few.[174] It is impossible to predict whether they constitute the beginning of a trend by the FDA to deny formal evidentiary hearings where the agency feels such hearings will serve no useful purpose. It is doubtful that they will be carried over into the food standards area where hearings have traditionally been held on broad policy questions. Further, if the agency attempts to deny hearings in cases where substantial economic interests are involved, judicial review and ultimate invalidation of the no-hearing practice is likely to follow.

My view is that the present trend—if there is a trend—to deny hearings in doubtful cases should not be encouraged. As long as section 701(e) remains in effect, it is preferable to simplify and rationalize hearing procedures rather than to engage in the doubtful legal practice of simply denying a hearing altogether.[175]

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[174] The FDA also denied a request for a formal evidentiary hearing in the *Statement of Policy Concerning Oral Contraceptive Labeling Directed to Users* proceeding. 35 Fed. Reg. 9001 (1970), a proceeding under § 701(a), not § 701 (e). The FDA proposed a warning to "pill" users as a package insert, a proposal that was strongly opposed by the medical profession and the drug industry. A consumer group requested that the disclosure be considerably strengthened, and further requested a public hearing so that it might present "in great detail factual data concerning the dangers of the pill and evidence demonstrating the necessity of providing women with accurate information about the pill. However, the FDA denied the request for a hearing on the ground that "a public hearing is unnecessary and would delay the implimentation of these regulations. Essentially, all of the objectors are agreed that patients require full information for the safe use of the oral contraceptives. The only issue is how best to assure that they have it." 35 Fed. Reg. 9001, 9002 (1970). Informally, one FDA representative stated that a hearing on this matter would have been a "disaster." Later the Commissioner justified before a congressional committee the refusal to hold a hearing as follows: "I concluded that a public hearing was not necessary for the further development of the facts and would instead delay implementation of a policy which I regard as plainly in the patient's interest." *Regulatory Policies of the Food & Drug Administration, Hearing Before the Subcomm. on Intergovernmental Relations of the House Comm. on Gov't Operations*, 91st Cong., 2d Sess., at 11 (1970).

[175] The recommendation as approved appears in the Appendix, paragraph I.

APPENDIX

RECOMMENDATION OF THE ADMINISTRATIVE CONFERENCE

In conducting rulemaking proceedings pursuant to Section 701(e) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 371(e) (1970), the Food and Drug Administration of the Department of Health, Education, and Welfare should adopt the following procedures:

A. Informal Opinions

During the pendency of a section 701(e) proceeding, the FDA should encourage requests addressed to it for informal written opinions as to the applicability of the proposed regulations to specific situations so that potential participants can determine whether it is necessary for them to participate further in the proceeding. The agency should respond to such requests to the extent it has views on the subject. Informal opinions issued pursuant to this recommendation should be made publicly available as required by the Freedom of Information Act, and the agency should consider publishing the most important such opinions in the Federal Register.

B. Delineation of Issues in the Notice of Hearing

The FDA should consider the "statement of issues" in the Notice of Hearing as the first step in isolating the questions to be considered at the formal hearing. To this end, it should:

(a) Amend its regulations to state that the "statement of issues" is not jurisdictional, but may be augmented or revised at the prehearing conference or hearing by order of the hearing examiner.

(b) State explicitly in the notice that while the agency is required by statute to support every aspect of the stayed regulations by substantial evidence, the issues to be considered at the formal hearing will generally be limited to the issues as augmented or revised.

(c) Formulate the "statement of issues" to the extent practicable in terms of areas of disagreement rather than in the ultimate language of the statute itself.

C. The Prehearing Conference

1. The FDA should make more effective use of the prehearing conference to isolate the areas of disagreement and narrow the scope of the hearing. To this end:

(a) The hearing examiner should normally require each participant (including the agency), at an early stage of the prehearing conference, to distribute to the other participants a written statement summarizing the testimony and proof to be adduced by witnesses called by the participant. The statement should include the names of prospective witnesses, the nature of the testimony of each witness, and a list of documentary evidence to be introduced. Documentary evidence referred to in written statements should

be made available by each participant for inspection and copying by any other participant. After the distribution of written statements, the prehearing conference should seek to establish the precise areas of disagreement. The hearing examiner may direct that discussion of issues be conducted off-the-record, but all statements as to areas of disagreement should be reduced to writing or be the subject of a verbatim transcript approved by the participants.

(b) The hearing examiner may require written objections by participants to the areas of disagreement as stated by the Government in the notice of hearing, and may receive oral or written argument in connection with such objections.

(c) The hearing examiner should describe in writing the areas of disagreement, and in the absence of surprise, cross-examination at the hearing should be limited to the areas of disagreement, as defined at the prehearing conference.

2. The prehearing conference should (i) identify the witnesses to be cross-examined, (ii) determine whether the examination is to extend beyond the witness' direct testimony, and if so, define the scope of the examination, (iii) determine whether restrictions should be imposed on cross-examination, (iv) identify documents for admission into evidence, (v) establish hearing dates, deadlines for distributing written direct testimony, and the sequence in which witnesses will be produced for cross-examination, (vi) establish the routine use of standard scientific treatises and (vii) establish the manner in which the qualifications of expert witnesses are determined. In the absence of surprise or unexpected developments, procedures and time periods established at the prehearing conference should be adhered to at the hearing.

3. If the proceeding is a complex one and the hearing is to be held in stages, the foregoing procedures should be applicable only to the first stage, and should be repeated for subsequent stages. Discretion as to the scheduling of such further stages should be vested in the hearing examiner.

D. The Conduct of the Hearing

1. The hearing should be conducted so as to encourage submissions of evidence in written form and discourage excessive oral examination or cross-examination. To this end the FDA should adopt regulations specifying that direct testimony should normally be submitted in written form, though where appropriate, the witness may be permitted by the hearing examiner to supplement his written direct by a short oral direct presentation. Generally, all participants should be required to distribute their written direct testimony before any witness is produced for cross-examination, and the distribution of the written direct testimony by the proponent of the proposed regulation should precede the distribution of written direct testimony by other participants.

2. The hearing examiner should exercise substantial authority over cross-examination in order to eliminate irrelevant or cumulative testimony and to expedite the hearing. Cross-examination which does not relate to the

areas of disagreement as defined in the prehearing conference should be excluded as irrelevant, though the hearing examiner should have authority to modify the description of the areas of disagreement at the hearing where appropriate to prevent prejudice to any participant. Examination relevant to any matter at issue should be permitted even though not raised by the witness's direct testimony if (i) within the knowledge, competence or expertise of the witness, and (ii) at the prehearing conference the participant desiring to cross-examine the witness specifies the areas to be covered by the cross-examination and shows that the proposed examination will produce testimony which cannot conveniently be introduced by direct testimony. The participant producing such witness may be permitted to cross-examine the witness as to testimony beyond the scope of his direct testimony.

3. If several participants with common interests desire to cross-examine a witness, the hearing examiner should encourage the participants to select a lead attorney or attorneys to conduct the cross-examination. In the absence of a showing of prejudice, participants with common interests should be grouped by the hearing examiner, and participants in a group should not be permitted to cross-examine witnesses called by other members of the group.

E. Obtaining Information and Documents from the FDA

1. The FDA should routinely make available to any participant prior statements of a witness produced by the agency which are in its files and which relate to the subject matter of the expected testimony if (i) the statement was made before the person agreed to become a witness for the agency, or (ii) the statement was published by the witness. "Statements" should include written statements signed or adopted by a witness or a recording or transcription of an oral statement made by the witness but should not include investigative reports, internal agency memoranda or the like which the agency would not be required to produce under the following paragraph.

2. The FDA should routinely make available upon request all unprivileged factual information in its files which relates to the subject matter of the hearing. Documents which contain such information should usually be made available upon request, whether or not the production of such documents may be required under the Freedom of Information Act. In considering such requests the agency should proceed on the assumption that disclosure is presumptively required in every case. Refusal to disclose should be based only on strong reasons, for example that the information represents trade secrets, or possible violations of the Act by non-participants, or internal memoranda the disclosure of which would seriously hinder the effective operation of the agency. The exceptions referred to in the preceding sentence should be construed more narrowly than the similar language in the Freedom of Information Act has been construed by the agency in the past. If the agency refuses to provide requested information or documents, it should to the maximum extent feasible provide summaries or descriptions or excerpts of information appearing in such documents.

3. Requests for information from FDA files for purposes of the hearing

should be accepted after the notice of hearing is issued and generally should cease when the hearing begins. The hearing examiner should be vested with authority, subject to interlocutory review by the agency to the extent permitted by its rules, to rule on questions relating to production of information, documents and prior statements of witnesses, and to issue appropriate orders to protect the interest of any participant or other person.

F. Ex Parte Communications

1. The FDA should amend section 2.104 of its regulations, 21 CFR § 2-104, to clarify that disclosure of ex parte communications under that section is required if:

(a) The communication is with or to the Commissioner, Deputy Commissioner or presiding hearing examiner;

(b) The communication occurs after the publication of the notice of hearing;

(c) The communication is (i) from a non-agency participant, the attorney appearing on behalf of the agency at the hearing, or a member of the FDA staff assisting such attorney at the hearing, and is not served on or communicated to all participants, or (ii) is from a person not a participant and not an agency employee; and

(d) The communication relates to the substantive issues involved in the proceeding as described in the notice of hearing or to the desirability of adopting regulations which have been stayed and are the subject of the hearing.

2. Section 2.104 should be further amended to require that disclosure of an ex parte communication should include a statement or summary of the information imparted or contentions advanced in the communication.

3. The agency should also amend its regulations to give an opportunity to participants to introduce evidence or argument to rebut facts or contentions made in any ex parte communications, disclosure of which is required by section 2.104.

4. The Commissioner, Deputy Commissioner and presiding hearing examiner should refrain from soliciting ex parte communications after the notice of hearing is issued.

G. Separation of Functions

1. The Department of Health, Education, and Welfare should adopt organizational changes within the Office of General Counsel so that the attorneys who prepare and conduct a section 701(e) hearing do not participate in the preparation of the tentative or final order. Legal assistance to the Commissioner of the FDA and the Secretary of HEW on such matters should continue to be provided by the Office of the General Counsel even though hearing attorneys are subject to oversight and control by the General Counsel and his subordinates.

2. Members of the staff of the agency who assist the agency attorney

at the hearing should not participate in the preparation of the tentative or final order.

H. Participation by Citizen Groups

The FDA should urge lay participants not represented by counsel to file statements or participate in the proposal stage of the proceeding rather than to act as a formal participant in the hearing. Such persons who desire to have their views made part of the formal record should be permitted to testify orally and in narrative fashion on the record at the formal hearing without being "called" by one or more of the participants. This recommendation is not applicable to persons, groups or agencies who are represented by counsel.

I. Denial of Hearings by FDA

No purpose is served in holding evidentiary hearings when the ouly issues in dispute involve purely legal disputes or will not affect the ultimate outcome of the proceeding. However, the agency should grant public hearings where the objections set forth in the request for hearing, if true, would invalidate the proposed regulation. Hearings should be granted when a prima facie showing has been made that an objection which meets this standard does exist. If the issues involved in such hearings are not those which are suitable for development at a formal trial-type of hearing, the agency should employ procedural devices to limit the scope of the hearing, produce most evidence and testimony in written form, and expeditiously create a formal record on which the correctness of the agency's factual conclusions may be tested.