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FAIR HEARING IN ADMINISTRATIVE RULE-MAKING: A RECENT EXPERIENCE UNDER THE FEDERAL FOOD, DRUG AND COSMETIC AND FAIR PACKAGING AND LABELING ACTS

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In promulgating regulations to govern the labeling of foods under the Fair Packaging and Labeling Act, the Commissioner of Food and Drugs, despite the objections of adversely affected parties, denied all requests for a public hearing. In this article the author reviews the hearing provisions of the Act, analyzes the position taken by the Food and Drug Administration, and concludes that the failure to grant a trial-type hearing on the labeling regulations was legally indefensible.

PROBABLY the most controversial topic in food and drug law during the 1960's has been the Fair Packaging and Labeling Act. The first Fair Packaging and Labeling bill was introduced in 1962,[1] following extensive investigative hearings by the Senate Antitrust and Monopoly Subcommittee.[2] The congressional hearings held from 1963 to 1966 provided ample opportunity for expression by both proponents and opponents of the legislation.[3] Despite the extensive congressional hearings, Congress in the provision finally adopted[4] did not generally specify standards for the labeling of con-

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[1] *See* S. 3745, 87th Cong., 2d Sess. (1962).

[2] *See* Hart, *Can Federal Legislation Affecting Consumers' Economic Interests Be Enacted?*, 64 MICH. L. REV. 1255, 1257 (1966).

[3] *Id.* at 1257-58.

[4] 15 U.S.C. §§ 1451-61 (Supp. II, 1967). The Fair Packaging and Labeling Act of 1966 was intended to enable consumers to obtain accurate information as to the net

sumer commodities in the Act, but rather, merely authorized the Food and Drug Administration and the Federal Trade Commission to fix these requirements and prohibitions in administrative regulations.[5] The Commissioner of Food and Drugs, upon publication of proposed regulations[6] on March 17, 1967, solicited comments concerning his proposals.[7] Over 300 comments were filed;[8] the Commissioner modified his regulations and re-published the amended provisions[9] as required by law.[10] Persons adversely affected were given 30 days to file objections and requests for a public hearing.[11]

quantity of contents of consumer commodities and to facilitate value comparisons. *See* Fair Packaging and Labeling Act § 2, 15 U.S.C. § 1451 (Supp. II, 1967). It provided generally that it was illegal to distribute a packaged consumer commodity in interstate commerce unless the commodity was labeled in conformity with regulations which provide for a statement of the name and place of business of the manufacturer, packer, or distributor, a uniform location for the net weight statement of the commodity, and uniform type sizes for the net contents statements on packages of commodities of substantially the same size. *Id.* § 4, 15 U.S.C. § 1453 (Supp. II, 1967). The Act also authorized certain discretionary regulations. *Id.* § 5, 15 U.S.C. § 1454 (Supp. II, 1967). However, no discretionary regulations have been yet promulgated.

[5] The Secretary of Health, Education and Welfare was given authority to promulgate regulations governing foods, drugs, devices, and cosmetics, and the Federal Trade Commission was given authority to promulgate regulations governing all other consumer commodities. Fair Packaging and Labeling Act § 5 (a), 15 U.S.C. § 1454 (a) (Supp. II, 1967). Since most consumer commodities not exempted by the Act are foods, drugs, devices, and cosmetics, the greater burden of regulation was placed on the Food and Drug Administration (acting under the Secretary of Health, Education and Welfare) rather than the FTC. The scope of the FTC's authority is not yet clear, although that authority certainly includes detergents and paper napkins. The extent of the FTC's authority may be defined more precisely in its revised regulations which are still unpublished.

[6] 32 Fed. Reg. 4172 (1967). The Federal Trade Commission also published proposed regulations under the Act. 32 Fed. Reg. 9109-12 (1967).

[7] Section 6 (a) of the Fair Packaging and Labeling Act, 15 U.S.C. § 1455 (a) (Supp. II, 1967), describes the procedure the FDA must follow in promulgating regulations. The Act directs that both the Food and Drug Administration's and the Federal Trade Commission's regulations be promulgated subject to judicial review in conformity with the Federal Food, Drug and Cosmetic Act §§ 701 (e)-(g), 21 U.S.C. §§ 371 (e)-(g) (1964). Congress expressly recognized in the Fair Packaging and Labeling Act that hearing could be required under this procedure when it stated that hearings "authorized or required" for the promulgation of the regnlations could be held before an officer designated by the Secretary or the Commission. *See* Fair Packaging and Labeling Act § 6, 15 U.S.C. § 1455 (Supp. II, 1967).

[8] 32 Fed. Reg. 10729 (1967).

[9] *Id.* at 10729-34.

[10] The Fair Packaging and Labeling Act requires that the FDA's regulations be promulgated pursuant to the provisions of subsections (e), (f), and (g) of § 701 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 371 (e)-(g) (1964). Section 701 (e) (1) requires the republication of the regulations as a "proposed order." 21 U.S.C. § 371 (e) (1) (1964).

[11] *See* 32 Fed. Reg. 10729, 10733 (1967). This procedure is required by § 701 (e) (2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 371 (e) (2) (1964), and § 6 (a) of the Fair Packaging and Labeling Act, 15 U.S.C. § 1455 (a) (Supp. II, 1967).

Almost 50 communications were received by the Commissioner in response to the republication some of which requested a public hearing.[12] The Commissioner considered the objections, made a few minor amendments, and denied all requests for a public hearing.[13] Thus, although all interested persons had been given a full and fair opportunity to state their views concerning the proposed legislation in oral testimony before Congress, the same opportunity was not made available to them when the regulations were promulgated by the Commissioner of Food and Drugs. The regulations, not the Act, prescribed the specific labeling requirements for consumer commodities and the Commissioner's refusal to grant a public hearing on the labeling requirements has been the subject of wide criticism in the food industry.[14]

THE RIGHT TO A TRIAL-TYPE HEARING UNDER THE ACT

It is well established that there is no constitutional right to a hearing when an administrative agency is engaged in rule-making.[15] As Mr. Justice Holmes has stated:

> Where a rule of conduct applies to more than a few people, it is impracticable that everyone should have a direct vote in its adoption. The Constitution does not require all public acts to be done in town meeting or an assembly of the whole.[16]

However, section 701 of the Federal Food, Drug and Cosmetic Act[17]—which is, in effect, incorporated in the Fair Packaging and Labeling Act[18]—has heretofore been regarded as the outstanding example of a statute which compels the use of trial techniques, including a hearing with testimony and cross-examination, in rule-making.[19] The Commissioner's virtually unprecedented action[20] in denying a public

[12] 32 Fed. Reg. 13277 (1967).

[13] *See id.*

[14] *See, e.g.*, Burditt, *Fair Packaging and Labeling—The Cost to Consumers*, 22 FOOD DRUG COSM. L.J. 542, 545-46 (1967).

[15] *See, e.g.*, Willapoint Oysters, Inc. v. Ewing, 174 F.2d 676, 694 (9th Cir. 1949), *cert. denied*, 338 U.S. 860 (1950); T. CHRISTOPHER, CONSTITUTIONAL QUESTIONS IN FOOD AND DRUG LAWS 22 (1960); 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 7.06 (1958).

[16] Bi-Metallic Inv. Co. v. State Bd. of Equalization, 239 U.S. 445 (1915).

[17] 21 U.S.C. § 371 (1964).

[18] *See* Fair Packaging and Labeling Act § 6(a), 15 U.S.C. § 1455(a) (Supp. II, 1967).

[19] 1 K. DAVIS, *supra* note 15, § 6.06.

[20] The closest precedents appear to be Dyestuffs & Chems., Inc. v. Flemming, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960); Cook Chocolate Co. v. Miller

hearing deserves detailed review because it is apparently a significant change in the procedures followed by the Food and Drug Administration. Since few litigated cases have considered the right to a public hearing in rule-making under the Federal Food, Drug and Cosmetic Act, such a review must rest primarily upon the legislative history of the Act.

The legislative history of the Federal Food, Drug and Cosmetic Act of 1938 includes extensive debates on the procedure for promulgating regulations. Congress believed it was very important that a trial-type hearing be held before a regulation became effective. The bill recommended to the House of Representatives by its Committee on Interstate and Foreigu Commerce provided that: "The Secretary, on his own initiative or at the request of any interested industry or substantial portion thereof, *shall* hold a public hearing upon a proposal to issue, amend, or repeal any regulation . . . ."[21] Further, the Secretary was to base his decision on the proposed regulation only upon substantial evidence of record presented at the hearing and the order was to contain detailed findings of fact based upon that evidence.[22]

The House Report which accompanied this bill stated:

> A proposal to issue, amend, or repeal any such regulation is to be made by the Secretary of Agriculture on his own initiative, or by the interested industry or a substantial portion thereof, and the Secretary is required to set the proposal for hearing. . . .
>
> This will prevent the pocketing of proposals to issue, amend, or repeal a particular regulation and eliminate application of the 'negative order' doctrine which denies court relief where the executive officer merely fails to take any affirmative action.
>
> If as a result of the hearing on any proposal, the Secretary determines to issue, amend, or repeal the regulation, the action taken may be based only on substantial evidence of record at the hearing. Similarly, the action of the Secretary in failing to carry into effect any proposal for issuance, amendment, or repeal of a regulation set for hearing must rest on a like basis. In either instance detailed

(D.D.C. April 1950), *reported in* V. KLEINFELD & C. DUNN, FEDERAL FOOD, DRUG AND COSMETIC ACT—JUDICIAL AND ADMINISTRATIVE RECORD 1949-50, at 251 (1951) (judgment for the administrator); Cook Chocolate Co. v. Miller, 72 F. Supp. 573 (D.D.C. 1947) (motion to dismiss denied). These cases are reviewed at text accompanying notes 34-49 *infra*.

[21] S. 5, 75th Cong., 3d Sess. § 701 (e) (1938) (emphasis supplied) (*reprinted in* C. DUNN, FEDERAL FOOD, DRUG AND COSMETIC ACT—A STATEMENT OF ITS LEGISLATIVE RECORD 793, 810 (1938)).

[22] *See id.*

> findings of the facts on which the action of the Secretary is based are required to be made public as a part of his order. It follows that if the order of the Secretary is to be valid, the Government must have placed in the record at the hearing its evidence in support of the action taken and thereby afford opportunity for persons affected to controvert viva voce the Government's evidence. 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.[23]

In support of the above quotation, the House of Representatives in its report cited a then-current Supreme Court case,[24] *Ohio Bell Telephone Company v. Public Utilities Commission*,[25] which illustrates the type of hearing and findings of fact intended by Congress. The *Ohio Bell* case began with a proceeding to revise telephone rate schedules. One of the key issues in the proceeding was to determine the fair value of Ohio Bell's property. The Public Utilities Commission determined the value of the telephone company's property as of a certain date and then took judicial notice of published price trends and other material which it used to adjust the valuation for other years. On appeal, the principal issue was whether the Public Utilities Commission had denied the telephone company a fair hearing by taking judicial notice of price indices and other evidence outside the official record. The Supreme Court of Ohio upheld the Public Utilities Commission and the United States Supreme Court reversed on the ground that: "The fundamentals of a trial were denied to the appellant when rates previously collected were ordered to be refunded upon the strength of evidential facts not spread upon the record."[26] The Supreme Court also held that the proceedings were subject to another objection:

> From the standpoint of due process—the protection of the individual against arbitrary action—a deeper vice is this, that even now we do not know the particular or evidential facts of which the Com-

[23] H.R. REP. No. 2139, 75th Cong., 3d Sess. (1938) (*reprinted in* C. DUNN, *supra* note 21, at 815, 824).

[24] *See id.*

[25] 301 U.S. 292 (1937).

[26] *Id.* at 300.

> mission took judicial notice and on which it rested its conclusion. Not only are the facts unknown; there is no way to find them out. . . .
>
> . . . .
>
> [H]ow was it possible for the appellate court to review the law and the facts and intelligently decide that the findings of the Commission were supported by the evidence when the evidence that it approved was unknown and unknowable?[27]

While Congress believed it was essential that a hearing be given before the promulgation of any regulation and that the regulation be based only upon evidence presented at a hearing, Congress also feared that industry would submit an endless succession of repetitive proposals to amend regulations, thereby keeping the Secretary in useless and perpetual public hearings. A group of consumer organizations protested that the provision making it mandatory for the Secretary to go through the whole process of public hearings whenever an industry is dissatisfied with a regulation was completely unjustified and likely to hamper enforcement activities.[28] A minority report of the House Committee on Interstate and Foreign Commerce noted that:

> If . . . any substantial proportion of such manufacturers, demanded a public hearing on a proposal to amend or repeal a regulation previously validated by the courts after litigation under subsection (f), the Secretary would have no alternative but to hold such a hearing . . . .
>
> . . . .
>
> In most of the industries affected by the bill there are sufficient minorities, vociferously opposed to any form of regulation, to form a substantial proportion of the industry. These could be depended upon in practically every instance in which a regulation is required for the protection of public welfare to resort to the tactics above described and prevent indefinitely the effectuation of the purpose of the law.[29]

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[27] *Id.* at 302-03.

[28] *See* C. DUNN, *supra* note 21, at 750. Senator Copeland, sponsor of the bill in the Senate, had this statement inserted in the Record immediately following the Senate's passage of the bill. *Id.* at 746.

[29] *See* H.R. REP. No. 2139, *supra* note 23. The House bill contained a provision stating that within ninety days after the Secretary issued a regulation, any person adversely affected could seek to enjoin the Secretary from enforcing the provision in any district court in the United States. C. DUNN, *supra* note 21, at 810. There-

Representative Lea felt that the bill deprived the Secretary of all discretionary powers. He therefore offered an amendment[30] to allow the Secretary, on his own initiative, "or upon an application of any interested industry or substantial portion thereof *stating reasonable grounds therefor,*"[31] to hold a public hearing upon a proposal to issue, amend, or repeal any regulation, and it was so enacted into law.[32]

The Federal Food, Drug and Cosmetic Act's rule-making procedure thus followed two fundamental principles:

1. Proposals for rule-making which were initiated by industry and were not supported by reasonable grounds could be denied by the Secretary without a public hearing;

2. Proposals for rule-making which were initiated by the Secretary, or initiated by industry and supported by reasonable grounds, had to be given a public hearing, and could only become effective after the Secretary had made detailed findings of fact based upon evidence presented at that hearing.

Under this procedure, no regulation could ever be made effective without first having been the subject of a public hearing.[33] The initial litigation concerning the right to a public hearing, *Cook Chocolate Company v. Miller,*[34] involved the first of these prin-

fore, by continuing to advance repetitive proposals, industry could have prolonged delay of enforcement of the regulation and kept the Secretary perpetually involved in either public hearings or injunction proceedings.

[30] 83 CONG. REC. 7776 (1938) (remarks of Representative Lea). The Food and Drug Administration in Cook Chocolate Co. v. Miller, 72 F. Supp. 573 (D.D.C. 1947), later tried to argue from Representative Lea's words that the FDA was given absolute discretion to determine when public hearings should be called and that the exercise of this discretion could not be reviewed. *See* Levine, *The Cook Chocolate Case—An Effort To Compel the Initiation of Administrative Proceedings,* 4 FOOD DRUG COSM. L.Q. 172, 179 (1949). However, this does not seem to be a fair interpretation of the legislative history of the Act. See text accompanying notes 40-45 *infra.* Congress was concerned about repetitive proposals for rule-making and did not believe the Secretary should be compelled to hold public hearings on such matters. Hence, Congress did not want to deprive the Secretary of all discretionary powers. However, there is no evidence that Congress intended to give the Secretary absolute discretion; indeed, with the exception of repetitive proposals or proposals not sponsored by a substantial portion of industry, the evidence indicates that a public hearing was regarded as a necessity.

[31] 83 CONG. REC. 7899 (1938) (remarks of Representative Lea) (emphasis added).

[32] Federal Food, Drug and Cosmetic Act § 701 (e), 52 Stat. 1055 (1938), *as amended,* 21 U.S.C. § 371 (e) (1964).

[33] *See* ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 32-33 (1947); Austern, *The Formulation of Mandatory Food Standards,* 2 FOOD DRUG. COSM. L.Q. 532, 574 (1947); Markel, *Reviewing Food Standards,* 6 FOOD DRUG COSM. L.J. 191, 201 (1951); *Developments in the Law—The Federal Food, Drug and Cosmetic Act,* 67 HARV. L. REV. 632, 666-68 (1954).

[34] 72 F. Supp. 573 (D.D.C. 1947).

ciples—whether a proposal was supported by reasonable grounds and was therefore entitled to a public hearing. The plaintiff, Cook Chocolate Company, had proposed an amendment to the standard of identity for cholocate which would permit the fortification of this food with vitamins, alleging in support of its proposed amendment that the British Ministry of Food had announced that chocolate was the best medium for administering vitamin concentrates and that the United States Army and Red Cross had used substantial quantities of vitamin-enriched chocolate to maintain proper diets of soldiers and under-nourished persons. The Federal Security Administrator refused to hold a public hearing on the proposal, saying it was not supported by reasonable grounds, and the Cook Chocolate Company sought a declaratory judgment to compel the hearing.[35]

The Government's motion to dismiss the complaint was overruled.[36] A court hearing was held thereafter and the company failed to prove the facts alleged in its petition to amend the chocolate standard.[37] In light of the company's failure, the court held that the Administrator's refusal to grant a hearing was not arbitrary or illegal.[38]

The reasoning underlying the *Cook Chocolate* case was not very satisfactory to either the Food and Drug Administration or industry. The Administration apparently believed that the power to call a public hearing is discretionary and that the denial of a public hearing because the petition is not supported by reasonable grounds cannot be reviewed by any court.[39] The FDA's argument was based on Representative Lea's words in offering the reasonable-grounds amendment to the House bill:[40]

> The bill provides that on the request of an industry or a substantial portion of it the Secretary shall hold a hearing. The authorities of the Department of Agriculture objected to this

[35] The Cook Chocolate Company also sought a declaratory judgment that its chocolate with vitamins was not barred by standards of identity which did not permit the use of vitamins in chocolate. However, this was held not to be a proper subject for declaratory judgment. *Id.* at 574.

[36] *Id.*

[37] Cook Chocolate Co. v. Miller (D.D.C. April 1950), *reported in* V. KLEINFELD & C. DUNN, *supra* note 20, at 251.

[38] *Id.* at 252.

[39] *See* Levine, *supra* note 30, at 172.

[40] *Id.* at 180.

provision, claiming that it deprived the Secretary of all discretionary powers.

I shall offer an amendment at the proper time providing in substance that when reasonable cause is shown the Secretary shall call the hearing. This will obviate any dispute over that question.[41]

The FDA reasoned that the dispute about hearings was obviated by giving the Secretary complete discretion to determine whether a hearing should be granted.

However, it is difficult to reconcile this conclusion with the remainder of Representative Lea's comments. Immediately preceding the words relied upon by the FDA, Representative Lea said:

I wanted to call the attention of the House to the particular regulations that are affected by this court review, but on account of the limited time I will not at this time enumerate those powers. For the present it is sufficient to say that they are very broad and very important. *It is these broad powers that no man should seek or want to exercise unless the court has a reasonable right to review his conduct from the standpoint of arbitrary action.*[42]

In the same speech, the Congressman stated:

[W]e must not ignore the fact that the people deserve protection against arbitrary and capricious government, against inexperience and ignorance by the departments which exercise this semilegislative authority.[43]

Therefore, considering Representative Lea's comments in their entirety, it seems likely that he intended to permit court review of the denial of a public hearing. Such a conclusion is consistent with the other legislative history in the House[44] and with the words of the statute to the effect that if reasonable grounds are shown, the Secretary *shall* call a public hearing.[45] The court in *Cook Chocolate*

[41] 83 CONG. REC. 7776 (1938) (remarks of Representative Lea).

[42] *Id.* (emphasis added).

[43] *Id. See also* Salthe, *Food Standard Making—What Did Congress Intend?*, 6 FOOD DRUG COSM. L.J. 174, 176 (1951): "Congress did not intend to delegate to the Secretary the same latitude that it exercises in enacting a law. . . . Congress intended to guard against any arbitrary action on the part of the Secretary in the promulgation of standards."

[44] See text accompanying notes 23-33 *supra*.

[45] Federal Food, Drug and Cosmetic Act § 701 (e), 21 U.S.C. § 371 (e) (1964); *cf. Developments in the Law—The Federal Food, Drug and Cosmetic Act*, 67 HARV. L. REV. 632, 668 n.283 (1954) (stating that it is arguable the statute compels such review). Quite apart from the merits of the *Cook Chocolate* case, the FDA's denial of a public hearing was regarded by one authority as an extraordinarily undesirable and unwise ad-

clearly did, in fact, review the denial of the hearing to determine whether it was an abuse of discretion.[46]

The *Cook Chocolate* case was not very satisfactory to industry because the plaintiff was given his opportunity to prove the facts underlying his petition in court rather than before the Secretary. In its ruling, the court seems to have failed to consider fully the nature of a public hearing. A public hearing is not a confrontation between the plaintiff and the Secretary; it is a proceeding at which *all* interested persons can offer evidence.[47] Thus, if the plaintiff's grounds were prima facie reasonable, the court erred in dismissing the complaint because it was at least possible that other interested persons would have appeared at the hearing and offered evidence supporting the plaintiff's arguments. Furthermore, in dismissing the complaint because of the absence of "competent evidence" to support the asserted grounds, the court may have overlooked the fact that evidentiary rules are much more informal at administrative hearings than in judicial proceedings.[48] Administrative agencies have wide discretion in the admission of evidence and other procedural matters; therefore, a possibility also existed that the plaintiff's evidence would have been competent to support his assertions had the hearing been before the Secretary rather than the court. In short, a denial of a public hearing is similar to the dismissal of a complaint,

ministrative determination. Austern, *Section 403(g) Revisited,* 6 FOOD DRUG COSM. L.J. 181, 183 (1951).

[46] Cook Chocolate Co. v. Miller (D.D.C. April 1950), *reported in* V. KLEINFELD & C. DUNN, *supra* note 20, at 251. A contrary conclusion would have placed excessive power over the food industry in the hands of the FDA. Some regulations define the composition of foods which cannot be sold except under the label "imitation." *See* Forte, *Definitions and Standards of Identity for Foods,* 14 U.C.L.A.L. REV. 796 (1967). By refusing to permit amendments to these regulations, the Secretary could arbitrarily freeze the composition of all foods and preclude all future improvements. These were probably the very broad powers which would have concerned Representative Lea were they not subject to judicial review. See text accompanying note 42 *supra.* The regulations are the same type as those involved in the *Cook Chocolate* case. Hence, where a clear abuse of discretion can be shown, the courts should order a hearing since a contrary approach could deny the public a significantly improved food product. *Developments In the Law—The Federal Food, Drug and Cosmetic Act,* 67 HARV. L. REV. 632, 668 (1954).

[47] The statute itself so provides. *See* Federal Food, Drng and Cosmetic Act § 701 (e) (3), 21 U.S.C. § 371 (e) (3) (1964).

[48] *See* Cook Chocolate Co. v. Miller (D.D.C. April 1950), *reported in* V. KLEINFELD & C. DUNN, *supra* note 20, at 252. The dismissal of the complaint apparently resulted from a procedural tangle in which the plaintiff succeeded in getting his petition and supporting documents introduced but did not have a witness qualified to testify concerning their contents. The complaint was later dismissed when the documents were found not to be competent evidence. Levine, *supra* note 30, at 175-76.

and if the grounds in the petition are reasonable, the hearing should be held before the administrative agency rather than the court.[49]

In the late 1940's and early 1950's, it became apparent that the excessive formality of the rule-making procedures of the Federal Food, Drug and Cosmetic Act impeded the issuance of non-controversial regulations.[50] The Food, Drug and Cosmetic Law Section of the New York State Bar Association, therefore, sponsored an amendment to reform the procedures for promulgating FDA definitions of the composition of foods. Endorsed by both food manufacturers and the Secretary,[51] the proposed amendment was patterned after section 507 of the Federal Food, Drug and Cosmetic Act.[52] Among the more important changes the amendment made in the procedure for promulgating regulations defining foods were the following:

1. The Secretary or any interested person showing reasonable grounds therefor could propose a regulation.[53] Under the prior procedure, regulations had to be initiated by the Secretary or a substantial portion of an industry. The 1938 Act had been interpreted to permit only basic food manufacturers and fabricators to propose amendments, while manufacturers and sellers of ingredients for foods could not suggest such changes.[54] The amendment thus

[49] *Cf.* Levine, *supra* note 30, at 181: "The issues raised by the complaint were essentially legal, not factual, and the so-called trial seemed particularly inappropriate for their determination." *See also* Administrative Procedure Act § 10, 5 U.S.C. § 1009 (1964), providing that except so far as statutes preclude judicial review, or agency action is by law committed to agency discretion, judicial review is available. Recent decisions of the Supreme Court make it clear that jndicial review will not be denied unless there is persuasive reason to believe that such was the purpose of Congress. *See* Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967); Abbott Laboratories v. Gardner, 387 U.S. 136 (1967); *cf.* L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE AGENCIES 363 (1965) ("Presumptively, an exercise of discretion is reviewable for legal error, procedural defect, or 'abuse.'").

[50] *See, e.g.*, Markel, *supra* note 33, at 191. *See also* Goodrich, *Patchwork on a Crazy Quilt of Administrative Procedures*, 10 FOOD DRUG COSM. L.J. 604, 606-07 (1955).

[51] *See* 1954 FDA ANNUAL REPORT, *reprinted in* V. KLEINFELD & C. DUNN, FEDERAL FOOD, DRUG AND COSMETIC ACT—JUDICIAL AND ADMINISTRATIVE RECORD, 1953-1957, at 664, 681 (1958). *See also* Markel, *Proposed Simplification of Food Standards Procedures*, 8 FOOD DRUG COSM. L.J. 227, 236 (1953) (reporting the action of the Food, Drug and Cosmetic Law Section of the New York State Bar Association).

[52] 21 U.S.C. § 357 (1964); *see* Markel, *Reviewing Food Standards*, 6 FOOD DRUG COSM. L.J. 191, 202-03 (1951).

[53] *See* 21 U.S.C. § 371(e) (1964).

[54] *See* S. REP. No. 1060, 83d Cong., 2d Sess. (1954) (*reprinted in* 1954 U.S. CODE CONG. & AD. NEWS 2126, 2128). *See also Hearings on H.R. 5055 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. 7 (1953);

broadened the class of members of the food industry who could propose regulations.[55]

2. The revised procedure gave the Secretary an initial opportunity to determine industry's reaction to a proposed regulation before public hearings. Regulations proposed under the 1938 Act were published prior to a public hearing. Under the revised procedure, a suggested regulation was published; interested persons were given an opportunity to state their views; and, finally, the Secretary proposed an order to which all adversely affected parties could file specific objections and request a public hearing.[56] Thus, if a public hearing were held, the Secretary knew from the objections which portions of his order were disputed and what the grounds for the dispute were.[57]

3. The revised procedure eliminated public hearings on noncontroversial regulations.[58] Under prior procedures, all regulations, even those to which there was no opposition, were given a formal public hearing at which the Food and Drug Administration presented evidence to support each portion. The requirement that the Secretary make detailed findings of fact substantiating the suggested provisions resulted in a record for judicial review even on minor amendments.[59] Under the revised procedure, hearings and detailed findings of fact were eliminated when no objection was raised to the proposed regulation.

The proposed amendment, called the Hale Amendment, was enacted in 1954,[60] thereby revising the statutory procedure so far as standards of identity for foods were concerned. In 1956 a statutory addition to the Hale Amendment was enacted which extended the new procedure to all FDA regulations.[61]

While the Hale Amendments were intended to permit the Secre-

Markel, *Proposed Simplification of Food Standards Procedures,* 8 FOOD DRUG COSM. L.J. 227, 234 (1953).

[55] *See* S. REP. No. 1060, *supra* note 54.

[56] *See* Act of April 15, 1954, ch. 143, § 1, 68 Stat. 54, *as amended,* 21 U.S.C. § 371 (e) (1964).

[57] As noted in the House hearings, the bill gave the basic industry an opportunity to be heard at the initial stages of rule-making. *See Hearings on H.R. 5055, supra* note 54, at 12.

[58] *See* Markel, *Proposed Simplification of Food Standards Procedures,* 8 FOOD DRUG COSM. L.J. 227, 235-36 (1953).

[59] *See* S. REP. No. 1060, *supra* note 54.

[60] Act of April 15, 1954, ch. 143, § 1, 68 Stat. 55.

[61] Act of August 1, 1956, ch. 861, § 2, 70 Stat. 919.

tary to forego public hearings on noncontroversial regulations, it is perfectly clear that they were not intended to eliminate these sessions when a party desired to make a record for judicial review. Support for this interpretation is found in the 1954 House Hearings, wherein the representative of the Food, Drug and Cosmetic Law Section of the New York State Bar Association, who was virtually the only witness, testified that in his understanding, the bill would allow *any* party to demand a hearing.[62] Further, in 1954 the Secretary of Health, Education and Welfare wrote to the House Committee, stating:

> The bill would greatly facilitate noncontroversial changes in food standards regulations. It would eliminate the necessity for public hearings and the establishment of a record of testimony and exhibits where, after due notice, it developed no one opposed the change.[63]

The Senate report similarly stated that enactment of the bill would eliminate the requirement for formal hearings except where such a hearing was desired for the purpose of providing a basis for judicial review when the objecting party found the ultimate regulation still objectionable.[64]

The 1956 legislative history was equally clear. As stated by the Secretary of Health, Education and Welfare:

> On the narrow issues about which there is controversy, any interested person affected by a proposed regulation could, by filing a petition, initiate the formal procedure, including a public hearing, establishment of the public record on which our action would be based, and review of our action in the United States Courts of Appeal. Thus, no substantial rights of any person would be relieved of protection, while government, the public and industry are relieved of the costs and expenditures of time in holding hearings on points about which we all agree.[65]

Likewise, the Senate report on the 1956 amendment stated that where the proposed regulations were not controversial, the bill would remove mandatory following of formal rule-making procedures.[66] Thus, in supporting the Hale Amendments, industry still believed

[62] *See Hearings on H.R. 5055, supra* note 54, at 7.

[63] This letter is part of S. REP. No. 1060, *supra* note 54.

[64] *See* S. REP. No. 1060, *supra* note 54.

[65] This letter is part of S. REP. No. 2752, 84th Cong., 2d Sess. (1956) (*reprinted in* 1956 U.S. CODE CONG. & AD. NEWS 4105-06).

[66] *See id.*

that it had retained the right to a public hearing whenever any member found a proposed regulation objectionable.

In 1959, *Dyestuffs & Chemicals, Incorporated v. Flemming*[67] first considered the sufficiency of objections and requests for a public hearing under the Hale Amendments. The Commissioner of Food and Drugs had issued a prohibition of the unrestricted use of certain coal-tar colors on the ground that these colors were not "harmless" as required by law. Regulations governing coal-tar colors were then promulgated under section 406 of the Act,[68] and these regulations were subject to the section 701[69] procedure as revised by the Hale Amendments. The petitioner, Dyestuffs & Chemicals, Inc., filed objections and demanded a public hearing on the proposed regulation, alleging that the colors were harmless under their intended conditions of use. When the petitioner's request for a public hearing was denied, it sought to have the regulations set aside by the Court of Appeals for the Eighth Circuit. After the filing of the petitioner's objections, the Supreme Court decided the case of *Flemming v. Florida Citrus Exchange*,[70] in which it held that unless coal-tar colors were *harmless,* they were not to be certified. Further, the court held that the Secretary did not have the power to license the use of coal-tar colors on the basis of the varying tolerances for harmful contents.[71] This controverted Dyestuffs' primary basis for its hearing request—that the colors were not harmful in the amounts in which they were being used, atlhough they were harmful in greater amounts.[72] The circuit court reasoned that a public hearing was unnecessary since even if the petitioner prevailed on his issues, the Secretary's order would still have to be valid under the Supreme Court's decision in *Florida Citrus.*[73] The *Dyestuffs* case thus turned upon the point that the petitioner had not asserted legally valid issues concerning the propriety of the Secretary's regulation.

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[67] 271 F.2d 281 (8th Cir. 1959), *cert. denied,* 362 U.S. 911 (1960).

[68] *See* Act of June 25, 1938, ch. 675, § 502, 52 Stat. 1049. In 1960 Congress enacted the Color Additive Amendments to the Federal Food, Drug and Cosmetic Act which now govern regulations similar to those involved in the *Dyestuffs* case. *See* Federal Food, Drug and Cosmetic Act § 706, 21 U.S.C. § 376 (1964).

[69] 21 U.S.C. § 371 (1964).

[70] 358 U.S. 153 (1958).

[71] *Id.* at 163-67.

[72] *See* Dyestuffs & Chems., Inc. v. Flemming, 271 F.2d 281, 284 (8th Cir. 1959), *cert. denied,* 362 U.S. 911 (1960), in which petitioner's objections are in part reprinted. The objections admit that the colors are harmful when used in sufficient quantity.

[73] *Id.* at 285-86.

In reviewing *Dyestuffs,* it becomes apparent that the court explicitly placed only two limitations on the right to a public hearing:

1. The objections must raise issues material to the legality of the order involved; and

2. The issues must not be frivolous or inconsequential.[74]

The court rested these minimal limitations upon the statute itself, which provides that the purpose of a public hearing is to receive evidence relevant and material to issues raised by the objections.[75] The court's unequivocal intent was to avoid the futility of a hearing on issues which lacked substance.[76]

Even these minimal limitations, however, have a dangerous potential for misapplication.[77] When Congress enacted the Hale Amendments, it used as its model section 507 of the Federal Food, Drug and Cosmetic Act.[78] There was one important departure. Section 507 requires that both a proposal for a regulation and objections to a regulation be supported by reasonable grounds. While the Hale Amendments require that proposals for regulations initiated by industry be supported by reasonable grounds, objections need only state "the grounds therefor."[79] Thus, if an attempt were made to evaluate the grounds of objections to determine whether they were "reasonable" or frivolous or inconsequential, the Secretary would be asserting a power which was presumably deliberately denied to him by the sponsors of the Hale Amendments.[80] In short, the

[74] *Id.* at 286.

[75] *See* Federal Food, Drug and Cosmetic Act § 701 (e) (3), 21 U.S.C. § 371 (e) (3) (1964).

[76] "Where the objections stated and the issues raised thereby are, even if true, legally insufficient, their effect is a nullity and no objections have been stated. Congress did not intend the governmental agencies created by it to perform useless or unfruitful tasks." Dyestuffs & Chems., Inc. v. Flemming, 271 F.2d 281, 286 (8th Cir. 1959), *cert. denied,* 362 U.S. 911 (1960).

[77] *See* 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 6.05 (Supp. 1965).

[78] 21 U.S.C. § 357 (1964); *see* S. REP. NO. 1060, *supra* note 54; Markel, *Reviewing Food Standards,* 6 FOOD DRUG COSM. L.J. 191, 202 (1951).

[79] *Compare* Federal Food, Drug and Cosmetic Act § 507, 21 U.S.C. § 357 (1964), *with id.* § 701 (e) (2), 21 U.S.C. § 371 (e) (2) (1964).

[80] Markel, who was one of the chief sponsors of the Hale Amendments and virtually the only witness to testify in favor of the first Hale Amendment, was clearly aware of the fact that § 507 of the Act required a statement of reasonable grounds to accompany *objections. See* Markel, *Proposed Simplification of Food Standards Procedures,* 8 FOOD DRUG COSM. L.J. 227, 233-34 (1953). The inference is inescapable that the omission was deliberate. It also seems likely that had the proposed amendment required "reasonable grounds" for a hearing, it would have been resisted by industry. Industry acquiesced in the Hale Amendments because it still believed it would be given hearings when it desired.

Secretary's power is limited to determining whether the *issues* raised by objections are material or frivolous or inconsequential. The grounds stated in support of the issues may not be examined for reasonableness; they are simply included as a convenience to the Secretary to aid him in his preparation for the hearing.[81]

The rationale for this distinction would seem to lie in the nature of the public hearing. Once an issue is raised for public examination, all interested persons can participate and offer evidence.[82] It thus becomes totally irrelevant whether the objector's representations (or "grounds") in support of his objection can alone compel revision of the Secretary's order. Rather, the question is whether on the record as a whole—considering the evidence presented by all interested persons—the order is justified.[83] The objector by raising the issue merely starts the process through which the validity of the Secretary's order is ultimately decided.[84] When a factual issue is raised, the Secretary then bears the burden of proving the substantiality of the evidence supporting the regulation.[85]

The distinction between issues and grounds for objections will often be unimportant because the objector will make substantially the same allegations in both. The court in such a case can be ex-

[81] The FDA, however, takes the contrary view. Its administrative regulations state: "Objections must be supported by reasonable grounds, which if true, are adequate to justify the relief sought." 21 C.F.R. § 2.67 (b) (5) (1967). The FDA would thus by regulation supply the word "reasonable" which was omitted from § 701 of the Federal Food, Drug and Cosmetic Act. The difficulty with this approach is that it places the burden on the objector to allege facts equivalent to proving prima facie invalidity of the regulation. The legislative history of the Hale Amendments, however, supports the view that hearings were only eliminated when no one opposed a regulation. See text accompanying notes 61-67 *supra*. As Representative Hale stated in the 1956 congressional hearings: "Specifically the bill would do only one thing; it would eliminate the requirement for formal procedure and a formal record when all concerned are in agreement but would preserve the present procedure [*i.e.*, the necessity of a hearing] where a hearing is desired by any disagreeing party." *Hearings on H.R. 9547 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 84th Cong., 2d Sess. 9 (1956). The "present procedure" did not require objections to be accompanied by "reasonable grounds" to warrant a hearing.

[82] *See* Federal Food, Drug and Cosmetic Act § 701 (e) (3), 21 U.S.C. § 371 (e) (3) (1964).

[83] The test is substantial evidence. *See id.* § 701, 21 U.S.C. § 371 (1964); Federal Security Adm'r v. Quaker Oats Co., 318 U.S. 218 (1943). *See also* Austeru, *The Formulation of Mandatory Food Standards*, 2 FOOD DRUG COSM. L.Q. 532, 582-89 (1947).

[84] As Mr. Markel said in the 1953 House hearings: "Under the proposed bill formal hearings would be limited to issues first clarified and pinpointed by the filing of objections . . . ." *Hearings on H.R. 5055, supra* note 54, at 10-11.

[85] The Secretary must then prove such evidence as a basis for the detailed findings of facts required under § 701 (e) (3) of the Act, 21 U.S.C. § 371 (e) (3) (1964).

pected to reach the same result in deciding whether the issues are frivolous or inconsequential that it would reach in deciding whether the grounds for the objection are reasonable. In other situations, the distinction can be all-important. For example, assume that a food standard of identity is proposed which does not permit the use of a particular ingredient. If a manufacturer who uses this ingredient seeks a public hearing on the validity of the standard of identity because it bars his product from sale, he may not be entitled to that procedure.[86] If instead he seeks a hearing on the issue of whether the prohibition of this ingredient is supported by substantial evidence, and thus is reasonable and promotes fair dealing in the interest of consumers, he should be given such a hearing, even if the only "grounds" for his objection are that the standard bars his product.[87] The Secretary then must prove his "substantial evidence" and the objector can introduce testimony supporting the representations in his petition and all other relevant evidence whether or not mentioned in his grounds. In practice, therefore, it may be advisable to begin by drafting a set of issues which are relevant and material to the proposed regulation and to state these issues separately from the grounds when making objections.[88]

While only two limitations on the right to a public hearing were explicitly stated in the *Dyestuffs* case, the court's opinion certainly implied a third limitation—that the issues raised must be issues of

[86] Standards of identity inherently limit the composition of foods and thus prevent foods which do not conform to the standards from being sold except possibly as imitations. *See* Federal Security Adm'r v. Quaker Oats Co., 318 U.S. 218, 231-32 (1943); United States v. 306 Cases Containing Sandford Tomato Catsup, 55 F. Supp. 725 (E.D.N.Y. 1944), *aff'd sub nom.* Libby McNeill & Libbly v. United States, 148 F.2d 71 (2d Cir. 1945). *See also* 62 Cases of Jam v. United States, 340 U.S. 593 (1951). Hence the fact that an individual product will be barred by a standard cannot per se invalidate a proposed standard of identity, and the issue could be regarded as inconsequential. But sales in volume of a food containing a specific ingredient can give rise to the inference that consumers expect such an ingredient in a food and therefore that a contrary standard does not conform to the reasonable expectations of purchasers and consumers as required by law. *See* Forte, *supra* note 46, at 805-10.

[87] The issue of whether an order is supported by substantial evidence should always satisfy the requisite for a grant of a public hearing. By raising this issue, the objector demands only to know the evidence relied upon by the Secretary and asks only that the Secretary make a record which can be judicially reviewed.

[88] The objections also must show that the proponent will be "adversely affected" by the Secretary's order, must specify "with particularity" the provisions of the order deemed objectionable, and must request a public hearing. *See* Federal Food, Drug and Cosmetic Act § 701 (e) (2), 21 U.S.C. § 371 (e) (2) (1964). Occasionally objections are filed which do not request a public hearing. These objections probably have no legal status but may still be helpful in persuading the Commissioner that revisions of his order are desirable.

fact rather than pure questions of law if a public hearing is to be required.[89] The court apparently reasoned that since the statutory purpose of the hearing is to receive *"evidence,"* only objections raising factual issues justify a public hearing. One distinguished commentator takes a contrary view, reasoning that the statute makes it mandatory for the Secretary to call a hearing when objections are filed.[90] However, this view ignores the purpose of a public hearing and the legislative history of the Act which indicates that the public hearing was intended to provide a basis for detailed findings of fact by the Secretary.[91] Under the circumstances, it is very difficult to conclude that the statute was intended to require the Secretary to listen to oral arguments by all interested persons on the legal validity of his regulation.

While the Secretary does not have to listen to oral *legal* arguments, it should be recognized that some issues of law are factually based and that a public hearing is required on such questions. For example, one of the most commonly raised objections to an FDA regulation is that the proposed regulation is not supported by substantial evidence. Whether the evidence supporting the regulation is substantial is an issue of law. However, no court could intelligently weigh evidence which was not first established in the record of the case.[92] In such situations, a public hearing and detailed findings of fact by the Secretary become a necessity to provide a basis for judicial review in conformity with section 701 (e) (3) of the Act.[93] Thus, issues of law may or may not require a public hearing depend-

[89] This was clearly implied by the court's opinion, which quoted from Sun Oil Co. v. FPC, 256 F.2d 233 (5th Cir.), *cert. denied,* 358 U.S. 872 (1958): " 'The only benefit that would have inured to Sun by notice and hearing would have been the privilege of making a legal argument before the Commission. We find no requirement in the Natural Gas Act for notice and hearing in such a situation.' " Dyestuffs & Chems., Inc. v. Flemming, 271 F.2d 281, 287 (8th Cir. 1959), *cert. denied,* 362 U.S. 911 (1960); *cf.* Certified Color Indus. Comm. v. Secretary, 283 F.2d 622, 625 n.11, 628 (2d Cir. 1960).

[90] 1 K. DAVIS, *supra* note 77, § 6.05.

[91] *See* Federal Food, Drug and Cosmetic Act § 701 (e) (3), 21 U.S.C. § 371 (e) (3) (1964); text accompanying notes 22-28 *supra.*

[92] This was the problem which troubled the House of Representatives. As in the *Ohio Bell* case, the appellate court cannot determine the validity of the administrative agency's action when the evidence is unknown and unknowable. See text accompanying notes 24-27 *supra.*

[93] 21 U.S.C. § 371 (e) (3) (1964); *see* Certified Color Indus. Comm. v. Secretary, 283 F.2d 622, 628 (2d Cir. 1960), for an analogous situation in which a color additive regulation was set aside because the Secretary had failed to make the necessary underlying factual determination.

ing upon whether a reviewing court requires a record containing factual evidence to decide the issue of law intelligently.

Problems arise in determining whether factual evidence is required for judicial review of issues raised by objections. However, the polar points seem relatively clear. If the issue is whether the Secretary's action is arbitrary, it is equivalent to asking whether his action is supported by substantial evidence and a hearing is required. If the issue is whether the Secretary is within his legal authority, generally no hearing is required because the reviewing court can decide that question solely upon the basis of the statute and its legislative history. When it is difficult to determine whether or not factual issues have been presented, the proper procedure would seem to be for the Secretary to grant the hearing. Again, this is consistent with the indications in the legislative history of section 701 of the Federal Food, Drug and Cosmetic Act that hearings were to be liberally granted to objectors.[94] Such a position also recognizes that no one can predict what evidence will be offered at a public hearing and, therefore, that the right to offer such evidence should not be denied unless it is completely clear that there are no conceivable facts which would be beneficial to a decision.

From a policy, as well as a legal, viewpoint, it can be reasoned that the Secretary should be liberal in granting public hearings on close questions. A contrary approach raises the possibility of protracted litigation to determine whether a hearing is necessary, litigation which may consume more time and result in more expense to the Government than would have been caused by holding the hearing. Additionally, the granting of a fair and impartial hearing is likely to further cooperative relationships between the Government and industry, while the refusal to grant such a hearing can exacerbate such relationships and generate the suspicion that an administrative agency is acting arbitrarily. In fact, until the advent of the controversy surrounding Fair Packaging and Labeling Act regulations, hearings had generally been liberally granted and very few disputes had arisen concerning this matter.[95]

[94] Under the 1938 version of the Act, 52 Stat. 1055 (1938), a hearing was required for all regulations and the later Hale Amendments were only intended to waive hearings when everyone acquiesced in the proposed regulation. See text accompanying notes 50-66 *supra.*

[95] The only reported cases on this subject are Dyestuffs & Chems., Inc. v. Flemming, 271 F.2d 281 (8th Cir. 1959), *cert. denied,* 362 U.S. 911 (1960) (reviewed at text

AN ANALYSIS OF THE POSITION TAKEN BY THE FOOD AND DRUG ADMINISTRATION

The denial of a hearing on the proposed regulations governing labeling of foods under the Fair Packaging and Labeling Act raises almost every conceivable legal question which could be raised under section 701 (e) of the Federal Food, Drug and Cosmetic Act. In rejecting the requests for a public hearing, the FDA began with those objections which stated that the regulations exceeded the authority of the Commissioner of Food and Drugs. The Administration argued that these objections were without merit and that, in any event, the objections did not properly raise any factual issues which could be resolved through the public hearing procedure.[96] On the latter point, at least, the FDA's reasoning seems correct, since the objections raised purely a question of law which was not dependent upon factual issues.[97]

The same argument—that only an issue of law was raised—was used to deny the requests for hearing based on other objections. These objectors had stated that the name of the division of a corporation was sufficient for consumer protection and that the regulation requiring the actual corporate name in addition to the divisional

accompanying notes 67-76 *supra*); and Cook Chocolate Co. v. Miller, 72 F. Supp. 573 (D.D.C. 1947) (reviewed at text accompanying notes 34-49 *supra*). Analogous cases are Certified Color Indus. Comm. v. Secretary, 283 F.2d 622, 628 (2d Cir. 1960); and United States v. 353 Cases of Mountain Valley Mineral Water, 247 F.2d 473, 480 (8th Cir. 1957), *cert. denied*, 358 U.S. 834 (1958). The limited number of cases on the point bears witness to the lack of controversy between industry and the Secretary on this question. The *Mountain Valley Mineral Water* case indicates an interesting, although obvious, limitation on the right to a public hearing. The right to the hearing lies under § 701 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 371 (1964), but this right does not extend to interpretive regulations which do not have the force and effect of law and are not promulgated pursuant to § 701. *Id.*; *see* Administratvie Procedure Act § 4 (b) (3) (A), 5 U.S.C. § 553 (b) (3) (A) (Supp. II, 1967).

[96] *See* 32 Fed. Reg. 13276, 13277 (1967). One of the more interesting arguments on the legal validity of the regulations was raised by the Carnation Company. Carnation's objections, dated August 21, 1967, argued that the FDA's promulgations under the Fair Packaging and Labeling Act were invalid in their entirety. The company noted that the Act, by express provision, did not become effective until July 1, 1967. *See* Fair Packaging and Labeling Act § 13, 15 U.S.C. § 1461 (Supp. II 1967). The Act also requires that proposed regulations be promulgated for comments and then republished for objections. *Id.* § 6 (a), 15 U.S.C. § 1455 (a) (1964). The Commissioner of Food and Drugs actually promulgated the regulations for comment on March 17, 1967. 32 Fed. Reg. 4172 (1967). Carnation reasoned that no one could properly promulgate regulations under a statute which was not yet in effect. The company concluded that since the regulations had never been properly published for comment, all subsequent proceedings were invalid.

[97] See text accompanying notes 89-94 *supra*.

name was unreasonable.[98] Reasoning that the actual name of the corporation was required by the statute, the FDA rejected all requests for a public hearing on this issue.[99] However, it is arguable that the Administration's theory that only a question of law was involved has less validity here than it had in meeting contentions that statutory authority had been exceeded. While the statute directs the FDA to promulgate regulations requiring the specification of the name of the manufacturer, packer, or distributor on consumer commodities,[100] there are two possible interpretations of the statute. The first is that Congress in enacting the statute directed the FDA to require the use of the actual corporate name on consumer commodities. The second is that Congress merely gave the FDA discretion to require the use of that name which was most meaningful to consumers. If the latter interpretation is correct, the FDA should have granted the public hearing and permitted testimony on questions such as whether divisional names have through usage become more familiar to consumers than actual corporate names and whether requiring actual corporate names would result in any great hardship to those who had been using divisional names. Once these questions had been resolved, the FDA would have discretion to determine

[98] *See* Food Chemical News, Aug. 28, 1967, at 5. The American Bakers Association objected that many corporations cannot use their actual corporate names in some localities since other corporations have prior local rights to the use of such denominations. The Gorton Corporation was concerned with the difficulty of determining the actual corporate names of the manufacturer when several subsidiaries participated in production of the commodity but did not expressly demand a hearing. In the view of the Carnation Company, the regulations were arbitrary and the scope of the Commissioner's authority should have been scrutinized in a public hearing. Additionally, Sunkist Growers filed objections with the Hearing Clerk, dated August 17, 1967, on a related issue. Sunkist, a cooperative marketing association, noting that the regulation would require its trademark licensees to place their names on the labels, contended that this was unreasonable because: (1) Sunkist set the specifications for the product and, therefore, should be considered the manufacturer; (2) Sunkist, and not its licensees, had the only name which had significance to consumers; and (3) the regulation would cause economic waste by preventing group-buying of packages. Sunkist demanded a public hearing on the issue: "Whether it is necessary or desirable to require the identity of distributors or packers of trademark brand products which are distributed pursuant to a franchise licensed contract."

[99] *See* 32 Fed. Reg. 13276, 13277 (1967). Some of the objections and issues for a public hearing on the corporate name requirement were technically imprecise. However, the Commissioner's denial of a public hearing did not rest on that theory. He instead reasoned that the *statute required* the actual corporate name and that therefore the question of whether the corporate name was necessary could not be the subject of the public hearing.

[100] Fair Packaging and Labeling Act § 4 (a) (1), 15 U.S.C. § 1453 (a) (1) (Supp. II, 1967).

what names should be used.[101] Arguably, Congress intended the FDA to exercise precisely this type of discretion, since the Senate report on the Fair Packaging and Labeling Act stated that the regulations were to be promulgated insuring "adequate identification" of the manufacturer.[102]

Probably the two most serious challenges to the Commissioner's regulations were objections to his specification of the lower thirty percent of the label as the position for the net quantity declaration and his choice of type size for the net quantity statement. With regard to the lower thirty percent requirement, one company objected that:

> the proposed order is not based upon adequate evidence that it would either promote consumer interest, improve consumer information, or enable consumers to obtain accurate information as to the quantity of contents or facilitate value comparisons.[103]

Restated, the objector's position was that the Commissioner's order was not supported by substantial evidence. In addition, the same objector queried whether sufficient facts established the top, rather than the bottom, thirty percent of the label as the best location for the net quantity statement.[104]

In denying the requests for a public hearing, the Commissioner said that other locations could have been adopted for the net quantity

[101] The FDA made the same type of argument—that it had no discretion and therefore that only a legal issue was presented—in denying requests for a public hearing on its definition of the principal display panel of packages. *See* 32 Fed. Reg. 13277 (1967).

[102] *See* S. REP. No. 1186, 89th Cong., 2d Sess. (1966) (*reprinted in* 1966 U.S. CODE CONG. & AD. NEWS 4069, 4070). The phrase "adequate identification" would seem to imply that the regulations could require a denomination less than the actual corporate name if another name were shown by the facts to be "adequate."

[103] *See* Objections of The Kroger Company, dated August 18, 1967, p. 1, on file with the Hearing Clerk, 330 Independence Avenue, S.W., Washington, D.C.

[104] The Kroger Company's objections raised three issues: "1. Whether or not there are sufficient facts to support the order's requirement that the net quantity of contents statement be placed within the bottom 30% of the area of the label panel; 2. Whether or not there are sufficient facts to establish that the order is consistent with the best interests of the consumer in enabling the making of value comparisons in marketing; 3. Whether or not there are sufficient facts to establish that the consumer's ability to obtain accurate information as to quantity of contents and to make value comparisons would be best facilitated by a requirement that the net quantity of contents declaration be placed within the top 30% of the label panel." *Id.* at 2-3. Kroger offered to show in support of its objections that substantial numbers of packages were now labeled with their net contents in the upper 30% of the label and that price markings were usually placed within the same area. Kroger reasoned that value comparisons would be facilitated by placing the net quantity statement and price in closer proximity. *Id.*

statement but that no location was agreeable to all parties.[105] He further found that:

> [a] public hearing as to the best location is not required, nor would a hearing of opinions on other places where this information might be placed change the situation. Such opinions have already been presented to the Commissioner at great length. 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 selection has been offered, it is found that there is no basis for a public hearing on this issue.[106]

This ruling raises several serious questions. While lengthy opinions may have been presented to the Commissioner concerning the proper location requirement,[107] none of those opinions would have been sworn or considered competent evidence in any judicial proceeding, and none were subject to cross-examination. If any factual issues were raised by the objections, the Commissioner should have disregarded all of this *ex parte* evidence, held a public hearing, and based his decision only on evidence of record at that hearing.[108] The Commissioner's comment that the selection of the uniform location was to be made by him and not by popular vote also seems to miss the point. If objections were filed raising factual issues, the Commissioner should have made his selection only on the basis of evidence presented at a fair, impartial public hearing.[109] Then, if the Commissioner's selection of a location were reasonable, and supported by substantial evidence, it would be a proper selection even if it were not the best selection. Finally, the Commissioner's ruling that no substantial objection had been offered to the uniform location requirement seems completely erroneous. One of the objections

[105] 32 Fed. Reg. 13277 (1967).

[106] *Id.*

[107] The opinions presented to the Commissioner were merely informal statements of the views of interested parties.

[108] Section 701 (e) of the Federal Food, Drug and Cosmetic Act makes clear that when objections are raised, the informal views and comments are not evidence. The statute states: "Such order shall be based only on substantial evidence of record at such hearing . . . ." 21 U.S.C. § 371 (e) (1964). The Food and Drug bar has always regarded the right of cross-examination as vital to the fair resolution of factual issues. *See, e.g.,* Austern, *The Future of Mandatory Food Standards,* 9 FOOD DRUG COSM. L.J. 77, 84 (1954) (cross-examination is perhaps the best guarantee against occasional or inadvertent arbitrary action); Markel, *Proposed Simplification of Food Standards Procedures,* 8 FOOD DRUG COSM. L.J. 227, 236 (1953) (formal examination and cross-examination of witnesses has proved itself as one of the best, if not the best, procedures to insure a democratic process in resolving disagreements formally).

[109] See notes 21-32, 61-66, 107 *supra.*

alleged that adequate factual evidence supported neither the Commissioner's regulation nor the view that the regulation would promote the purposes of the statute. Though the substantiality of this objection would seem apparent, the Commissioner ignored it and focused upon another issue raised by the same objector—that the facts supported the contention that a location other than that chosen by the Commissioner was best. No reason was given for the Commissioner's conclusion that an objection stating that a regulation is not supported by adequate factual evidence is not substantial.[110]

[110] Arguably, the Commissioner erred on at least one other objection. The objector challenged the requirement that packages bear the words "net weight." The Commissioner overruled the objection on the ground that the proponent had not suggested alternative language. *See* 32 Fed. Reg. 13277 (1967). However, the objector had no responsibility to draft a regulation supported by substantial evidence; such a function was congressionally granted to the Commissioner.

Additionally, the Commissioner probably erred in ruling upon objections filed by those corporations which also filed requests for exemption of their products from the regulations. The apparent theory of this dual filing was that it gave full protection of the companies' legal rights. In practice, it had no such effect. The Commissioner noted in relation to the soft drink industry that "[s]everal objections involving the labeling of nonalcoholic beverages sold in bottles closed by crowns were submitted allegedly to protect the legal rights of the objectors in the event of the Commissioner not acting favorably on certain requests for exemptions that were submitted at essentially the same time. The Commissioner will consider requests for exemptions supported by good and sufficient reasons. Thus, objections seeking special exemptions in this category cannot be accepted as justifying a public hearing." 32 Fed. Reg. 13277 (1967). There is no statutory justification for denying objections and requests for a public hearing merely because an exemption petition is also presented. Further, some of the objectors raised legal issues which warranted a public hearing. *See, e.g.*, Objections of the Coca Cola Company, dated July 21, 1967, on file with the Hearing Clerk, 330 Independence Avenue, S.W., Washington, D.C. ("whether there was sufficient evidence to justify § 1.8 (a) and § 1.8 (b) and the supporting Finding No. 3 . . . dealing with the placement of the statement of identity.")

The Commissioner's action also put those filing both exemption petitions and objections at a procedural disadvantage. When objections are filed raising factual issues, the Commissioner must grant a public hearing. *See* Federal Food, Drug and Cosmetic Act §§ 701 (e) (2)-(3), 21 U.S.C. §§ 371 (e) (2)-(3) (1964). However, more than factual issues must be shown to get a hearing on exemption petitions. The petitioner must show: (1) a statement of facts supporting his petition, (2) that the petition is reasonable, (3) that the proposal will not unduly impinge upon the consumer's right to information, and (4) that full compliance with the law is impracticable or otherwise unnecessary. *See* Fair Packaging and Labeling Act Reg. § 1.1a (b), 32 Fed. Reg. 10730 (1967). Some persons who raised objections sufficient for a public hearing may, therefore, be denied such a procedure because their exemption petitions do not meet the detailed criteria of the Commissioner.

Even if all persons filing both objections and exemption petitions do ultimately get a hearing on their exemption petitions, this will not be equivalent to a hearing on objections. Under the Administrative Procedure Act, the burden of proof rests upon the proponent of a rule or order. *See* Administrative Procedure Act § 7 (c), 5 U.S.C. § 556 (c) (Supp. II 1967). *See also* 21 C.F.R. § 2.63 (Supp. 1967). The Commissioner would therefore have had the burden at all hearings on objections, while the objecting petitioners would have that responsibility at all hearings on exemptions.

Objections to the Commissioner's choice of type sizes were treated in a similar manner. One objector alleged that the type size established for packages having a principal display panel of twenty-five to thirty-five square inches was arbitrary and unreasonable.[111] The Commissioner reasoned that whatever type sizes were chosen, some persons would find them objectionable. He therefore concluded that this was a matter that the Commissioner had to decide, and not one warranting a public hearing.[112] Again the same fallacy exists in his reasoning. Though the Commissioner must decide the content of all regulations, the statute requires that when factual issues are raised, he make that decision only after a public hearing. Finally, in a belated attempt to avoid a public hearing, the Commissioner made some minor amendments to his final regulations[113] which tended to be favorable to industry.[114] However, consumers, as well as producers, have legal standing under the Federal Food, Drug and Cosmetic Act.[115] In modifying final regulations, both consumers and producers were deprived of an opportunity to object to the changes and seek a public hearing.[116] Although the changes

The most appropriate procedure under the circumstances would seem to have been for the Commissioner to proceed to a hearing on the proposed exemptions and to hold a decision on objections in abeyance pending resolution of the exemption requests. If the exemptions were granted, the petitioners would no longer be persons adversely affected by the order and their objections could be dismissed. If the exemptions were denied, these objections, together with all others raising factual issues, would be entitled to a further hearing; but the prior record on the exemption petitions could be received into evidence, thus satisfying the Commissioner's desire to avoid unnecessary duplication of evidence.

[111] *See* Objections of the Carnation Company, dated August 21, 1967, on file with the Hearing Clerk, 330 Independence Avenue, S.W., Washington, D.C. The regulation prescribed type sizes for packages having a label area of 25 to 100 square inches. Fair Packaging and Labeling Act Reg. § 1.8b (i) (3), 32 Fed. Reg. 10732 (1967). The Carnation Company, noting that this encompassed a large category of labels, suggested that lesser type sizes would suffice for packages having a label area of 25 to 35 square inches. Carnation said, "To be sure, some arbitrary point must be selected at which the content declaration type size must be moved up a notch. Our complaint is that the point given in § 1.8 (b) (i) (2)- (3) is not reasonable . . . . The regulation, then, is arbitrary and unreasonable." Objections of the Carnation Company, *supra* at 6-7.

[112] 32 Fed. Reg. 13277 (1967).

[113] *Id.* at 13277-78.

[114] Alterations were made primarily to meet industry objections. These changes included allowance of additional time for adding Zip Codes to labels of consumer packages, re-definition of the principal display panel of odd-shaped containers, and exclusion of declarations of numerical count from the servings category. Also, the requirement that dilution directions be placed on the principal display panel of the package was made optional rather than mandatory. *Id.*

[115] *See* Reade v. Ewing, 205 F.2d 630 (2d Cir. 1953), *noted in* Baird, *Right of Judicial Review,* 10 FOOD DRUG COSM. L.J. 285 (1955).

[116] A collateral problem under the Fair Packaging and Labeling Act regulations

were not significant, the approach followed by the Commissioner in making them was without statutory authorization.

CONCLUSION

The objections filed to the regulations promulgated by the Commissioner of Food and Drugs under the Fair Packaging and Labeling Act posed difficult questions concerning the necessity for a public hearing pursuant to section 701 (e) of the Federal Food, Drug and Cosmetic Act. However, as the foregoing analysis indicates, there can be little doubt that the Commissioner erred in uniformly denying all requests for a public hearing on his controversial labeling regulations.[117]

raised vestiges of *Cook Chocolate Co. v. Miller.* See text accompanying notes 34-39 *supra.* The National Canners Association filed a petition for exemption of smaller containers from the FPLA regulations. The Commissioner replied that the petition did not set forth reasonable grounds and, therefore, that publication of the petition as a proposed regulation was not warranted. *See* Food Chemical News, Oct. 2, 1967, at 8.

Additionally some objections were filed to a statement of policy promulgated by the Commissioner dealing with inventory of packages. These objections were apparently denied because they raised only an issue of law and because statements of policy are not subject to objections. *See* 32 Fed. Reg. 13277 (1967); *cf.* United States v. 353 Cases of Mountain Valley Mineral Water, 247 F.2d 473, 480 (8th Cir. 1957), *cert. denied,* 358 U.S. 834 (1958).

[117] At the Food and Drug Law Institute—Food and Drug Administration Educational Conference—held in Washington, D.C., on November 27, 1967, a Food and Drug Administration official suggested that the Commissioner's refusal to hold a public hearing might be justified by FPC v. Texaco, Inc., 377 U.S. 33 (1964). Considering rulemaking under the Natural Gas Act, the *Texaco* Court held that it was sufficient to permit interested parties to express their views in writing rather than in an oral hearing. The official suggested that the same philosophy applied to the Federal Food, Drug and Cosmetic Act, and, therefore, that the opportunity to submit written views satisfied statutory requirements. It should be noted, however, that the Commissioner himself did not rely upon this rationale in denying objections. In his denial he merely said that "none of the objections . . . warrant . . . holding of a public hearing . . . ." 32 Fed. Reg. 13277 (1967). The implication that the consideration of written comments and objections was a "hearing" is thus contrary to the stated reasoning of the Commissioner of Food and Drugs. More importantly, the equation of a hearing with written submission is inherently inconsistent with the Federal Food, Drug and Cosmetic Act § 701, 21 U.S.C. § 371 (1964). Section 701 (e) (1) provides that the proposed regulation will be published and that all interested persons will be given an opportunity to comment orally or in writing on the proposed regulation. The Secretary is then to consider the comments and republish the proposed regulation. 21 U.S.C. § 371 (e) (1) (1964). Sections 701 (e) (2)-(3) provide that persons adversely affected can file objections and demand a public hearing and that "the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative." *Id.* § 371 (e) (3). It is thus clear that *after* the filing of objections, interested persons must be given an opportunity to present evidence and be heard. Finally, any dispute about the type of hearing required by

Whenever a public hearing is required, it is to ensure that the administrative agency responsible for rule-making under the particular act listens to all of the relevant evidence and specifies the finding of facts underlying its regulations. A possibility always exists that the additional evidence presented at a public hearing may lead to significant improvements in the agency's proposed regulations. Even where improvement seems unlikely, a compatible working relationship between government and industry necessarily depends upon a mutual respect for the rule of law. While it may be argued that the failure to hold a public hearing on proposed administrative regulations is expedient, since it avoids delay,[118] expediency of this type is not without its costs. Both the public interest and the rule of law suffer when an administrative agency ignores the statutory right to a public hearing on its proposed regulations.

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the Federal Food, Drug and Cosmetic Act can be resolved by reviewing its legislative history which makes plain that an oral hearing with the right of cross-examination was intended. See text accompanying notes 21-27 *supra*. Until the controversy over Fair Packaging and Labeling, the Food and Drug Administration itself consistently interpreted § 701 as requiring an oral hearing. Since there has been no amendment to the Act justifying a different interpretation, the consistent and long-standing interpretation of the FDA would seem to be entitled to great weight in determining the proper construction of the statute. *Cf.* United States v. Zucca, 351 U.S. 91, 96 (1956).

[118] The expediency argument was raised by Food Chemical News, Sept. 18, 1967, at 9, when it stated: "The history of the FPLA food regulations assures Commissioner Goddard of good grades in President Johnson's course in achieving consensus. Despite the great number of adverse comments, and later of objections, to the regulations, FDA has managed to publish, republish, and make effective highly controversial regulations. This has been done rapidly. The luster of this politically desirable accomplishment would have been dimmed if a public hearing had been deemed to be necessary."