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Food Drug Cosmetic Law JOURNAL

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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TO THE READER

Question and Answer Panel of the Food and Drug Law Institute, Inc., and the Food and Drug Administration Eleventh Educational Conference. —The Question and Answer Panel held during the morning session of the Eleventh Annual Food and Drug Law Institute, Inc., and the Food and Drug Administration Educational Conference is featured on page 332 in this issue of the JOURNAL.

Members of the panel were: *William W. Goodrich,* Assistant General Counsel of the Food and Drug Division of the U. S. Department of Health, Education and Welfare; *H. Thomas Austern,* Member of the Washington, D. C. law firm of Covington and Burling; *Kenneth R. Lennington,* Salmonella Project Officer, FDA; *Edward Brown Williams* of Harter, Calhoun, and Williams; *J. Kenneth Kirk,* Associate Commissioner for Compliance, FDA; *Vincent A. Kleinfeld* of Kleinfeld and Kaplan and *John M. Newton,* Ph.D., a representative of Standard Brands Inc.

Question and Answer Panel of the FDLI-FDA Eleventh Educational Conference—Afternoon Session: Foods Workshop.—The article which begins on page 348 is a record of the afternoon session of the FDLI-FDA Educational Conference's Foods Workshop Question and Answer Panel. *Franklin M. Depew,* President of the Food and Drug Law Institute, was the moderator for both the morning and afternoon sessions. Members of the panel, in addition to some of those who participated in the morning session, were *Peter Hutt,* a member of the law firm of Covington and Burling; *George M. Burditt,* a member of the law firm of Chadwell, Keck, Kayser, Ruggles & McLaren; *Bernard F. Daubert,* Ph.D., Director of Nutrition at the General Foods Corporation, *John A. Kedzior,* a member of the Bureau of Education and Voluntary Compliance of the Food and Drug Administration, and *Alfred Barnard,* Director of the Bureau of Regulatory Compliance of the FDA.

Questions and answers reflecting the material discussed in the Drug Panel Workshop at the afternoon session of the Conference were presented in the April, 1968 edition of the JOURNAL.

Fair Hearing in Administrative Rule-Making: A Recent Experience Under the Federal Food, Drug and Cosmetic and Fair Packaging and Labeling Acts. —In this article, a reprint from the *Duke Law Journal,* which begins on page 366, *Wesley E. Forte* presents his views concerning the necessity of a public hearing to discuss regulations designed to govern the labeling of foods under the Fair Packaging and Labeling Act. Heretofore, the Commissioner of Food and Drugs has denied all requests for a public hearing, after considering the objections of all interested persons and making few minor amendments to the regulations. In support of his personal views on the subject, Mr. Forte reviews the hearing provisions of the Act, and discusses the position of the Food and Drug Administration concerning the legal aspects of the problem. Mr. Forte, a member of the Pennsylvania Bar, is an attorney with the Borden Company.

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Question and Answer Panel of the FDLI-FDA Eleventh Annual Educational Conference

The Following Material Is from the Morning Question and Answer Panel, Moderated by Franklin M. Depew, and Featured on November 27, 1967 at the Eleventh Annual Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration.

Questions Addressed to Mr. Goodrich

Q. On several occasions, types of scientific information which should be included in our New Drug Applications (NDA's) have been suggested to us by scientific representatives of The Food and Drug Administration (FDA). What authority do such verbal recommendations carry?

A. They carry only the reviewer's judgment on what will be needed to get the NDA approved. Of course, everyone should understand—I believe they do understand—that a firm has the right at any time to stand on the data as submitted and request the filing and adjudication or judgment on the NDA as it stands. Our regulations guarantee a prompt hearing on any such case in which a difference of opinion arises between the reviewer and the company over the adequacy of the data.

Q. In a recent response to Mr. Jarman, some U. S. Pharmacopeia (USP) articles were stated to be exempt devices. Does this constitute a change in the traditional attitude of FDA that all USP articles are drugs and not devices?

A. The whole issue of what is ostensibly a device or drug is now in the two courts—the 2nd Circuit in the *AMP Suture* case and the 6th circuit in the *Difco Disc* case. My honorable opponent, Mr. Williams, is in the *Difco* case and there isn't any change in attitude that I know about over this. We did take the position in the New York Federal District Court that materials recognized in the USP were for that reason drugs, and Judge Tenny disagreed with us on that point but agreed that the product itself was a drug and a new drug.

Questions Addressed to Mr. Kirk

Q. Will you please review briefly the status of the proposed petition regulations in view of the comments filed by industry.

A. We received a large number of comments and, as Mr. Goodrich said this morning, many of them were directed toward the non- or the indirect-additive problem. Mr. Goodrich said he was sure our people are looking into it, or would be looking into it. I can assure you they are looking into it very seriously. I think that we ought to get these out early in 1968 but that's a "crystal ball" guess. I think we need revision of the regulations on food additive petitions to get better ones, to get them out. I happen to be the complaint department when people don't think they're getting service and it is really disconcerting, sometimes, to find that the reason that they didn't get service was because the petition itself was something of a mess.

Questions Addressed to Mr. Austern

Q. What is the relationship between lawyers and the food and drug press?

A. To quote Mr. Ambassador Abba Eban, who once called the relationship between politicians, diplomats, and the press "unilateral belligerency," I would just suggest this: Reporters, however zealous and pertinacious, very often do not understand that a lawyer cannot discuss his client's affairs publicly. A lawyer cannot argue his cases in the press. He simply cannot, with the applicable code of ethics, give press statements about his client's affairs. I think that is the most that I can say. It's very difficult when a fellow, whom you know and like, wants a story and you are not permitted to tell him about it. But I think any other operation—any other modus vivendi would destroy the attorney-client relationship and privilege. And it is the client's privilege.

Questions Addressed to Mr. Goodrich

Q. Do you agree with the Supreme Court on the effect of an FDA announced interpretation?

A. Of course I agree with the Supreme Court. We got beaten—and the surprising thing is that Mr. Austern got up here this morning and found me duplicitous. When I was saying that the regulations have the force and effect of law I was simply quoting from what the Supreme Court majority opinion did to us. They found us quite wrong in believing that there was such a thing as an interpretive regulation.

Moderator

I should like to commend to each of you Mr. Goodrich's speech in Honolulu last summer. I commend it to you because I have great difficulty in understanding it. As I follow the argument, there are some circumstances subscribed a little more strenuously than perhaps the Supreme Court did, in which an interpretive regulation may be challenged prior to its actual enforcement. Mr. Goodrich lays out some limitations—no factual issues. But as nearly as I can interpret the rest of it—the suggestion is that if you don't do it promptly they will plead laches—that is delay. If you do it too promptly—they may say there are fact questions so you can't do it that way. And I'm not too clear. I know a little bit about the case and the only thing I hope is that we don't have to keep arguing about it.

Mr. Goodrich

I certainly agree with the latter statement. My education in the case has been recent and intense, as you probably know, and so with that aside we can go to the next question.

Questions Addressed to Mr. Goodrich

Q. If physicians are so ill-equipped therapeutically, is it not the responsibility of the medical schools instead of the industry and its advertising?

A. I think its generally agreed among the profession, any realistic person in the profession, that there's been so much development in drug therapy and its been so fast, that a great many of today's physicians were not educated at all in medical schools about the products they are using in their practice. We agree of course that there is room and a need for the medical schools to greatly expand their teaching of drug therapy, but nonetheless this is the case in which

the prescription drug industry has moved into the post graduate education of a physician. Most of the education of the physician, once he leaves medical school, is supported one way or another by the advertising dollar and all we're asking is that it be truthful and informative.

2nd part of question:

Has anyone surveyed the practicing physicians as to whether or not they want a drug compendium?

A. This was a question raised by Mr. Stetler before the Nelson Committee and it is a good question. No one has made a "Gallup-type" poll of the profession over whether they would like to have such a compendium. We do know that they use "Physicians' Desk Reference" as one of the most important sources of information. It is a single volume of the kind of information we are talking about, but it's limited to those products that the companies seek to advertise there. For example, it doesn't have the complete line of any drug producer. We, in FDA, think it important to do two things. First, to have all drugs available and second, to have these descriptions made in a non-promotional and non-advertising style.

3rd part of question:

If private enterprise puts up the money for such a compendium, will they have any say in its content?

A. Of course they will have a say in its content in terms of having the product approved through the new drug procedures—they initiate the package insert; they write it for themselves. We do some editing on it. There would be some further editing in the compendium in terms of a single write-up for a product. In the present PDR, for example, there are several write-ups of reserpine under trade names and they're not all the same. If we have a National Drug Compendium it wouldn't be possible within a ten-foot shelf to have all the different brand name products separately described. But it would be possible to have a uniform package description for the products that are the same and it would be, in our thinking at least, complete full opportunity for industry to participate. Dr. Goddard has said, and I can repeat I'm sure with his approval that, "we prefer that this whole thing be done by private industry." But we're thinking of moving ahead if that doesn't come about.

Questions Addressed to Mr. Lennington

Q. You mentioned organisms other than salmonella that should be eliminated from our foods and drugs. Please elaborate and name them in order of their potential hazard to health.

A. I don't believe I would be able to name them in the order of their potential hazard to health. It's a case of getting a pathogen in the right place, at the right time, when it may produce a fulminating infection. With respect to the general group of organisms that we can expect to find in products that have been prepared under insanitary conditions, under conditions whereby they may be contaminated with human excrement, we have the E-coli. Of course there is always the possibility, and it is not infrequent, for shigella infections to affect large numbers of persons. We have clostridium perfringens. There is another organism, vibrioperihemoliticus, the extent of which we are not sure—in fact we know very little of its extent in this country now; yet it is by far the most common food borne infector in Japan and some of the Oriental countries. And of course we get into the area of viruses. It's been reported that there are somewhere in the vicinity of over 100 viruses that may occur in the human intestinal tract. It was on this basis that I made the observation, that what we do to control Salmonella has very definite benefits in controlling or preventing infections caused by these other intestinal occurring organisms.

Q. What consideration has FDA given to the long range possibility that over-sanitation will remove a large body of miscellaneous antigens that the population is exposed to, thus leading to a future catastrophe because of lack of wide immunity?

A. Frankly, I don't think that the Food and Drug Administration at this stage of the game has given much consideration to oversanitation. It has been our general experience, and I believe that the Communicable Disease Center (CDC) statistics will support our position, that we are a long way from reaching a salmonella-free or a salmonella-negative environment. And so long as we are having 20,000 reported cases of Salmonellosis per year, we are not approaching a state of sanitation and cleanliness that constitutes a hazard.

Questions Addressed to Mr. Austern

Q. Why does not the legal profession spell out the health and safety of the public as a foremost ethical consideration in the practice of law? Ahead of corporate profits?

A. Whoever wrote that I would like to take to a seminar—because I think it demonstrates what you can find in the Bible, Shakespeare, Chaucer, Jerry Bentham, and in this meeting in the way of a misunderstanding of the function of a lawyer. Without attempting to do that, I'll just offer three little things that might be worth thinking about.

A doctor doesn't inquire into the morality of a sick person whom he has been asked to advise as to therapy.

Most law enforcement, as any penetrating student of government knows, reflects high level, ethical, legal advice. If that were not true, there could really be no effect of law enforcement. The courts, the administrators, aren't able to carry it on. That is a fact of life.

And third, I think every administrative official knows that constructive solutions in the public interest very often are hammered out by the lawyers, both in government, and out of government.

Q. If key public health issues are not publicized i.e., are discussed only at closed Congressional hearings and other similar restrictive environments, how will the public become educated to these issues, which in some cases may mean life or death to them?

A. I hope it is clear and no one ever has or should disagree, that if there is imminent danger to health, the FDA must take to the air and to the newspapers and warn the public. Now beyond that, not every Congressman, every Congressional Committee staff, or every reporter, is truly competent to evaluate medical questions. Consequently, I suggest to the questioner that, if there is a life and death issue there is not only no inhibition, but there is a duty to bring it home to every American man and woman. And if there's not a question of life and death, then the FDA should use all available scientific and medical experts to get the answers. I think Mr. Goodrich adverted to the reference on efficacy of certain drugs to the National Academy of Science. That's the way to do it and not to have every reporter or every Congressman either scaring the public or giving them medical advice.

Questions Addressed to Mr. Kirk

Q. When will the code of Good Manufacturing Practices for foods mentioned by Mr. Goodrich be published?

A. I think my crystal ball here is pretty good. It should be in the Federal Register either late this week or early next week, and it

is being published as a proposal. We hope you people will look it over very carefully and let us know what you think of it. Incidentally, I might mention right here that when we put out proposals, every once in a while we get told, "Look what you got back. Everybody that wrote found something wrong with your proposal. Nobody wrote and said they liked it." And yet I am sure that some of these are liked by a great many people, but we don't get "we agree" letters very often. We did once.

Q. Incoming material is rejected by our Quality Control Inspectors in the receiving area. If we notify FDA, it is reported as seized at our plant without any acknowledgement that it had been rejected and refused by our personnel. Could this be changed to report it as seized while attempting delivery or after being refused delivery by our plant, thus not penalizing our plant by reflecting or insinuating that our plant uses substandard or unfit material?

A. When we get this kind of a report, which shows that the material was illegal, adulterated or what have you, at the time it was received in the plant, we proceed by seizure and the libel, of course, has to say where it is. Otherwise the Marshall wouldn't know where to go to make the seizure. But as far as the Food and Drug Administration is concerned, we put out no publicity that the XYZ Co. had some unfit material on hand. Furthermore, in our Notice of Judgment, which is published after the case is closed, we do not list the name of the firm where the goods were found, when the violation took place before the firm received the goods. The Notice of Judgment lists the name of the firm responsible for the violation.

Questions Addressed to Mr. Goodrich

Q. Please explain clearly just why it takes so long to find a hearing examiner for the dietary regulations hearings? Second, why are you calling it vitamin-mineral regulations?

A. The reasons for delay in obtaining a hearing examiner were *first,* Congress cut off our appropriations for paying for one to be borrowed. It forbade the use of funds to reimburse other agencies for a borrowed hearing examiner. And we have set about trying to recruit one through the Civil Service Procedures. On the second question, I might say I have nothing to do with that; the Hearing Examiner is not under my jurisdiction and not under my control. Mr. Kirk is undertaking the job of recruitment.

Q. Why are you calling it the "vitamin and mineral" regulations?

A. Simply, it's a shorthand method of describing what we were talking about. I apologize if I'm inadequate on that.

Comment by Mr. Kirk on first part of last question:

We did get from the Civil Service Commission a register of eligible hearing examiners, and there were seven names on the list. We contacted each of them and found four who thought they might be interested. We had conversations with each of the four and we thought we were just to the point of hiring the examiner, when the rules came out that for the time being we could not appoint anyone from outside the FDA to any job. I guess you could appeal to the White House if you just had to have the man, but for the moment we are blocked in that area and we're hoping that it will open up quite soon. We do have a couple of people who want the job, and frankly, one of them should be hired soon.

Questions Addressed to Mr. Goodrich

Q. Why was publication of Notices of Judgment discontinued? Excerpts in FDA Papers are fine but do not fill the same need.

A. The old system of publication was discontinued after a review by Mr. Cron, who is the Assistant Commissioner in charge of this sort of communications. We have cooperated with the FDA Papers in supplying them the short forms and the main advantage so far is that they are much more current. We all understand the need to put in some more facts and we are examining the possibilities of doing that, and at the same time keeping them current.

Q. The Senate has included Senator Long's Generic Drug Bill in the Social Security Amendments of 1967 passed last week. If this becomes law, what will FDA do to implement the National Formulary and other provisions of the bill which FDA apparently opposes at present?

A. The original FDA opposition to the Long Formulary Bill was based on different provisions than now exist. If the bill that was enacted last week becomes law we will have three jobs fundamentally. First, to prepare, in cooperation with the Formulary Committee, a formulary of drugs expressing or listing all those drugs that are likely to be needed within the age groups, along with adequate prescribing information, suppliers and supplementary price lists. We will be obligated to develop a special means, by 1970, in which we can assure the public of complete reliability of all drugs with the same generic

name but sold under a variety of trade names. We will be obligated to develop some additional prescribing information for the formulary for products that were never cleared through the new drug procedures. But the time lag allowed in Senator Long's bill was to allow us an opportunity to "tool-up" to handle the job.

Question Addressed to Mr. Lennington

Q. Have you established a negligible level of salmonella in foods?

A. No we have not. We have not attempted and I don't feel we are likely to try to set a tolerance for a pathogen or disease-producing organism in foods. Now, it's inescapable that there is essentially a built-in level by reason of our methodology. The salmonella determination is cumbersome; it is a slow and long drawn out one. Consequently, any laboratory is limited in the number of determinations it can make. Thus, when we are looking at ten or possibly twelve—25 gm. portions or we're checking possibly ten or twelve—100 gm. portions, instead of looking for salmonella in X tons of foods, actually we are checking 12 portions to determine if there's salmonella in it.

To repeat and to emphasize, we do not have a negligible level nor a tolerance for salmonella in foods. Of course you always encounter the situation where you must make some sort of administrative decision with respect to action based upon these particular results and the circumstances.

Questions Addressed to Mr. Austern

Q. In your opinion, is there any type of objection that could have been made to the Fair Packaging and Labeling Regulations which would have resulted in a hearing being ordered, on that objection, by the FDA?

A. In the first place, I hope it's clear that if the objection made to a final order is only a legal objection, the courts have held that no public hearing is necessary. Along with Mr. Goodrich I yield to the courts in a case in which I was clobbered. Beyond that, Mr. Burditt, who will speak this afternoon, has talked at some length on that particular issue. As far as I'm concerned this morning I would like to suggest only this. There's always been confusion about the purpose of a public hearing in section 701, which Congress provided after extensive debate between 1935 and 1938. Its primary purpose is *not* court review. Its primary purpose is that he who regulates is supposed

to come and set forth under oath, the facts on which he will regulate, remembering that the regulation becomes the law of the land and a penalty for violation is seizure, absolute criminal liability and the possibility of an injunction. Because of those sanctions, Congress provided this complicated, difficult, but all important requirement, namely, that he who regulates come and set forth the facts on which he bases his regulations. Now as far as going to court, I suspect that every experienced man and woman in this room knows that anybody who goes to court against the FDA has 2 strikes on him and properly so. On any court review my eloquent and able advocate friend, Mr. Goodrich, invariably wins. He talks about the public health, the judge grabs his tummy and never second guesses the FDA. Beyond that, the main purpose is what I've stated. Now as far as the details, the Fair Packaging regulation objections, I simply suggest that a man proposes and objects but the FDA disposes and in this instance they have.

Q. Communication with the public concerning a product in advertising seems to require startling, or stimulating statements to be effective. The consumer may even be known, if polled, to discount some of this poetic license. Ought advertising to be only literal and unimaginative?

A. It is a little difficult to penetrate this. I think we would grant the proposition that good advertising must at least be startling and stimulating in terms of attracting interest. It seems today to be done more with females than about the product. Now as to the second suggestion, that the consumer may even be known, if polled, to discount it, on all I've seen in this field, I quite agree. We seem to have a literate and intelligent population qualified to vote, and elect our representatives. I'm not sure that anyone ever thought the consumer was as stupid as some of the guardians would believe. But beyond that, we now have many statutes which make it clear that if there is a false and misleading statement in advertising, either directly or by implication, or because something is left out, it is actionable. More than that, in the field of food, drugs, and cosmetics, it is criminally actionable. It's actionable by injunction, if there is any public health question. And as far as prescription advertising is concerned I think it's better for me to give the card to Mr. Goodrich.

Mr. Goodrich

Nothing in any of our prescription drug advertising regulations, as they now exist, or as they are proposed to be placed in operation,

would require advertising to be either literal or unimaginative. And if you don't believe it, pick up Medical World News or any other comparable magazine and have a look at how the industry is communicating to the prescribers. We have made it clear from the very first effort in regulation in this field, that we're not opposed to the use of graphic and persuasive presentations for drugs. All we want them to be is truthful, and without misleading implications, and to contain in fair balance the adverse material along with the good. Now we've taken the position that advertising prescription drugs is different from advertising 100 millimeter cigarettes, or a new car or anything of that kind. And Congress has said that you do have to have, in the ads, a statement of the adverse effects along with the good. But the volume of prescription drug advertising has not gone down. The volumes of sales for prescription drug companies has not decreased. And we're confident that nothing in our proposals will interfere with good advertising practices.

Questions Addressed to Mr. Goodrich

Q. Is there any current indication that there will be a request for judicial review of the Fair Packaging and Labeling Administration (FPLA) regulations?

Second — when will final Fair Packaging and Labeling Regulations as they apply to drugs be issued? When will the above regulations be made effective?

A. We have no indication one way or another on the judicial review. The time runs out, I believe, December 19th and under the cases that we have in the Courts of Appeals, any interested consumer has enough interest to precipitate judicial review. We'll simply have to wait that time out, and once that time passes, it may even be possible to challenge the regulations at a later time.

Q. When will the regulations on drugs be issued?

A. We hope within the next ten days or two weeks.

Q. When will they become effective?

A. They will have an effective date arranged much similar to what we had on food to allow for the use in an orderly way of existing stocks and the transition to the new regulations.

Question Addressed to Mr. Kleinfeld

Q. What can a company do when a demand is made upon it under threat of action by the FDA, if the company does not believe that a

demand is warranted? Even though the company in the end may prove to be in the right, the damage is done by the adverse publicity.

A. Well, this is one of the most stultifying things to the lawyer in the Food and Drug area. Not infrequently a lawyer tells a client that what the client wants to do is correct and that the position of the FDA, in the lawyer's opinion, is dead wrong. Nevertheless, the company frequently says even though this is so, I am so scared of publicity that I just won't do what you say is permissible.

My answer is this. I have a sneaking suspicion that once in a while a government agency will start a regulatory action not based on a position that the government feels is sound, but on the belief, which often is true, that the company, because of the fear of publicity, will not defend. My answer to the question is this, and there is only one answer: The company puts the question to its attorney. If the attorney thinks that the demand is right, or probably right, you give the government what it asks for. If the counselor, however, says, in his opinion, the demand is wrong, you refuse the demand and you stand on your hind legs. And if the government starts a regulatory action, publicity or not, you defend.

Question Addressed to Dr. Newton

Q. What in your opinion is the outlook for workable solutions and voluntary compliance by industry, (*a*) by individual companies and (*b*) by industry associations?

A. My basic concept of law is that there must be voluntary compliance. In other words the governed must be willing to be governed. In my estimation, there is an excellent chance for voluntary compliance from industry. I believe that some very small companies may need a lot of assistance in this area. This opinion, I think, puts me in very good company because it so happens that Dr. Goddard said in a speech last Spring, "If I were not hopeful that business has the capacity to improve its ability for self-regulation, I would not spend this much effort discussing the matter. But I am optimistic." So am I.

Question Addressed to Mr. Austern

Q. If processing records are turned over to an FDA inspector, what protection does the manufacturer have that these will be kept confidential, if that person leaves the employment of the FDA?

A. As you know, the whole area of factory inspection is to be ventilated this afternoon. But I think a quick answer to this is, first — Title 18 of the Federal Criminal Code, as well as the provisions of the FDC Act, prohibits any employee from releasing confidential information. Second, it manifestly is a very elusive area. I know no solution because only in certain other areas of the world do they engage in brain-washing.

Question Addressed to Mr. Williams

Q. Dr. Goddard stated that the public is demanding better drugs, foods, and assurance of their safety and efficacy. Do you believe this hue and cry is really from the public or is it promoted by the FDA, so as to cause such reaction from the public?

A. I have no doubt that the public would like to have better foods, drugs, and cosmetics and better everything else which is in the marketplace. I also have no doubt that through certain consumer organizations, who have designated themselves as representatives of the public, that a certain hue and cry is being raised, with respect to the quality of the goods which are on the market. And I don't think anybody can doubt, after listening to Mr. Austern, that the FDA is making its contribution in this field.

May I make another comment since I'm talking? We heard this morning, a good deal about communication and information. This may seem tangential but I should like to say it anyway. This afternoon Peter Hutt is going to talk on Factory Inspection. I have no idea what he is going to say. But I hope that he will enter somewhat into the field of what the Food and Drug Inspector should tell to the employees of the companies whose premises he is inspecting. Under the statute as I read it, there is no requirement that the employee talk to the inspector, at least beyond the point of facilitating the inspection which the inspector is authorized to make under the statute. I hope that some consideration will be given to this proposition: that the employee, who really doesn't know, in this maze of regulations behind the inspection, that he doesn't have to talk to the inspector. I think, as a constitutional matter, and as a statutory matter, the FDA should consider telling him that.

Mr. Austern

I feel I ought to add one other comment on the question about employees who work for the FDA, then go out into business.

I've heard a great many complaints and apprehensions on that point. But I have never seen what I would regard as a fully documented case in which a man who worked for the FDA went out into industry and utilized information that he had obtained in the course of his official duties. If any such case ever was presented, I would have no hesitation in taking it to the FDA with complete confidence that they would institute prosecution, as a salutary example.

Of course people become educated, generally, but as far as giving away any trade secrets I have yet over 35 years to see what I would regard as a documented case that that has happened.

Mr. Williams

I hope that I was not misunderstood. I was not talking about FDA employees. I was talking about what the FDA inspectors should tell the employees of the company, whose premises they inspect.

Question Addressed to Mr. Kirk

Q. What is the FDA status of the private publication, Feed Additives Compendium? This sets forth levels of drugs and combinations thereof which may be added to animal feed. If the FDA is serious about its desire to have a national drug compendium, which appears to be aimed primarily at the prescription drugs, it might demonstrate its good faith by recognizing this publication.

A. I'm familiar with the publication and, in my opinion, as it is now set up, it is not in the category of the drug compendium that Dr. Goddard was speaking about this morning. Nevertheless, I would not for one minute say that it couldn't become a fully recognized publication, recognized by the FDA. You folks may remember that when we first came out with our Food Additive Regulations, we had quite a list of substances generally recognized as safe, and we said that these would be conditioned upon their being "food grade." Well, of course immediately, there was a great deal of interest in just what is "food grade" for each substance that someone wanted to use. The National Research Council of the National Academy of Science, undertook to set up a Food Chemical Codex which would have all of the specifications for a food grade item as listed in the Food Additive Regulations. They did this in very close cooperation with the scientists in the FDA. Perhaps you have noticed that the present edition of the book carries a letter from Dr. Goddard which recognizes that the specifications therein are in accord with the FDA's views as to what is "food grade."

Questions Addressed to Mr. Lennington

Q. What percent of the samples analyzed for salmonella are found to be positive?

A. I have no data on that, and if we did have data it would be misleading because the samples that we examine would be, you might say, biased. We will examine a large number of samples, where we have reason to suspect contamination. Furthermore, where we encounter manufacturing practices, plant sanitation, that would account for contamination, we sample that firm's products more heavily than the other firms.

Q. What is the status of the quick bacteriological test for salmonella detection?

A. I would hazard a guess that probably this refers to the fluorescent-antibody method. It is my understanding from our scientists that the fluorescent-antibody method is essentially still in a research and debugging status and is not ready for general use.

Questions Addressed to Mr. Goodrich

Q. I have a follow-up question on the first one asked, which was: — "On several occasions, types of scientific information which should be included in our NDA have been suggested to us by scientific representatives of the FDA. What authority do such verbal recommendations carry?" The person who wrote this one was not satisfied with my answer and says: Discussing generalities from the podium doesn't help. You say industry can appeal any disagreement. However, we feel we are repeatedly told, to "do what we tell you or you won't get the material through the FDA for an approved NDA."

What competent people like yourself say on the podium and what young, inexperienced medical and scientific FDA staff "tell us" in fact are two different things.

A. This indicates a lack of understanding of the routes of threshing out differences. Every one of these "young" and "inexperienced" scientific people is working within an organization. They have a supervisor and they have a Director of the Bureau of Medicine, and we have a commissioner, all of whom make their time available, in many instances, to hear disputes that can't be settled at a level below that. My answer was that, if a person ultimately could not thresh out a difference within the administrative give-and-take, that he has his right to insist on a filing over-protest and to take the thing on into a hearing and into the courts. But for those of you who do not know Dr. Goddard or his method of operation, or Dr. Ley and his, they have

been, I am sure many here will tell you, willing to meet and go over these points. I frequently receive telephone calls from lawyers about delays in handling NDAs. Sometimes even from Covington and Burling, but the points are that they do develop differences of view over the need for the data and the requirements but there are places to thresh this out and even legal means, if a person wants to carry them on.

Q. Since the title of this conference is communicating in the public interest how do you account for the Commissioner's early departure rather than waiting for an exchange of ideas?

A. I accounted for that on the ground that he is a 12-15 hour a day man. There are a great many of us here and every word said throughout this entire program will be gone over by him in great detail; his early departure does not in any sense mean a disinterest in this program.

Mr. Kirk

May I say he left me to keep the store too.

Mr. Austern

I can't object to Mr. Goodrich's commercials, but I think those of you who try to do a forthright and decent job on an NDA can do nothing but welcome his suggestions that there should be indexing, tables of contents, and a more orderly arrangement for the evaluation of material. I am constrained to suggest that nothing has ever been more frustrating than to get up a beautiful five-volume NDA with tabs and fine bindings and think that you really put the whole story out, only to discover that somebody in the old days would take your beautiful findings and rip them all out and take your tabs and throw them away and tie it up. And I hate to say this — with red cord — not red tape — but red cord so that your beautiful index and arrangement of material has all been conglomerated in a little bundle. I am constrained to add, that if each of us does this indexing and tabulating and arrangements that have been suggested which I think will contribute to expeditious consideration — I hope they won't rip them up.

Question from Mr. Williams to Mr. Goodrich

Q. I would like to ask Mr. Goodrich whether, in his view, the forthcoming Good Manufacturing Practice Regulations for the food industry will have the force and effect of law?

A. The Seventh Circuit Court said they would, the *Smith Canning* case. **[The End]**

Question and Answer Panel of the FDLI-FDA Eleventh Annual Educational Conference

Afternoon Session: Foods Workshop

The Following Material Is from the Afternoon Question and Answer Panel, Also Moderated by Franklin Depew, and Featured on November 27, 1967 at the Eleventh Annual Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration.

Questions Addressed to Mr. Daubert

Q. If General Foods would do all the control work anyway, regardless of the Food and Drug Administration (FDA) self-inspection project, what real benefit do you receive?

A. Let me point out that when I made that remark, in connection with the two products, you must remember now that the only two products that are a part of this self-certification project are a gelatin dessert and an egg custard mix. Prior to the institution of this self-certification program, we've had controls over the egg custard mix to such an extent that we believe we are over-controlling the product. And hopefully, out of this self-certification program we can get some agreement with the FDA as to the minimum controls that are necessary to assure consumer protection. We feel that will be a real benefit to us and also to the consumer.

Q. Self-certification agreements appear to provide increased communication from industry to the FDA, increasing FDA knowledge of industry practices. What are the gains for industry?

A. Well, I can only fall back on the quote by our Chairman that obviously this kind of a program will eventually develop into a closer cooperation between our industry and the FDA. I might point out that in the area of complaints we're only concerned about those com-

plaints that involve consumer protection, and that as part of the agreement, we are informed when the FDA gets a complaint concerning this area. And we feel that's very worthwhile. Now let me point out again that, if any of you are looking for very specific things that industry expects to get out of self-certification programs, I must confess I will not be able to give them to you. We are hopeful of course that, in the long run, as a direct result of this pilot program, there will be substantial agreement between FDA and ourselves in terms of the minimum number of control points. Hopefully it will cut down, in the future, on the number of inspections that might be made at any individual plant under such a program.

Questions Addressed to Mr. Barnard

Q. It is possible to purchase frozen eggs, from a processor, which are "certified salmonella free" by a U. S. Department of Agriculture (USDA) lab. Yet the same eggs can be sampled by an FDA lab and be found to contain salmonella, and the FDA can and does move against the owner of the eggs. How can the FDA and USDA justify their positions?

A. I have several comments. First, we seldom move against the owner of the eggs. We will move against the eggs because they are an adulterated food in interstate commerce which presents a potential hazard to the consumer. Secondly, as far as justifying the position is concerned, it is not a question of justifying the position. If it were a matter of position, there would be no justification. USDA certainly would not say we're going to let them ship eggs with salmonella, while the FDA says we're not.

We are talking here about a scientific problem. Those of you who listened to Mr. Lennington this morning heard some comments about the number of subsamples that it is reasonably possible to take and to examine and that occasionally the results of examinations by one organization don't agree with those by another. We are working closely with the USDA and are in constant touch with them. The development of Good Manufacturing Practice (GMP) guidelines in industries like nonfat dry milk where salmonella problems exist, have been worked out in close coordination with them to try to keep to a minimum episodes of this kind.

Q. Will GMP for the food industry be expanded to apply to intentional and incidental food additives?

A. The answer is no. If somebody thinks that we're going to try to substitute GMP's for the established food additive regulation procedures, we will not.

Q. What controls on substances that are generally as safe, other than quality suitable for food use, are contemplated by the Administration?

A. I assume this means under the GMP's and the answer is essentially the same as before. If it's generally recognized as safe (GRAS) for the intended use it will not be a matter of concern under GMP's. A companion question is asked about packaging materials having prior sanctions for safe use in intended applications. The answer is the same.

Q. What protection will the consumer receive from an imported food made under insanitary conditions?

A. There isn't any good answer to this. This is a problem that we face with imported foods ever since the passage of section 402(a). We are working on import problems with respect to drug GMP's. We have recently established an Office of International Affairs and one of the responsibilities of that office is to attempt to come up with some really workable answers to this problem. The Public Health Service (PHS) has solved it in the case of certain viruses, serums and toxins by simply excluding them. But that doesn't look like a feasible approach at the present time from the food standpoint.

Q. Are the GMP guidelines for nonfat dry milk, smoked fish and other products ready for distribution to industry upon request?

A. Yes, we'll be glad to distribute them to interested parties. Incidentally, they will eventually serve as a basis for the promulgation of the GMP appendices after the "umbrella" is published. And I might add that in some situations, we expect to furnish our inspectors with these inspectional guidelines, and then we make them available to others. However, they're really set up as inspectional guidelines. I put them out to our inspectors, let them acquire some experience with them, and let the affected industries acquire some experience with our inspectors working with them. And based on the feed-back from this process and from State officials, we shall polish them, if you please, into GMP appendices.

Q. Will there be a total bacterial specification for foods irrespective of pathogens?

A. In some cases there will be. In cases where there is sufficient scientific background, and I am sure most of you are familiar with the

extensive work that has been done on precooked frozen foods, this is an area where they very likely will be. In many other areas obviously there will not be.

Questions Addressed to Mr. Kedzior

Q. If a General Foods product under self-certification contains salmonella, will publicity releases be given to the press about recalls?

A. The program as it is set up with General Foods, contemplates that the finished products are going to be tested before they are released for distribution to the consuming public. They will not be released until after the tests are finished. Some of the items may be held in warehouses, which General Foods has in different sections of the country, but distribution for retail sale will not be made until after the product has been thoroughly tested to determine that it is not contaminated.

Should anything happen along the line that an item is distributed when contamination is uncovered and a recall has to be undertaken, it will be treated as any other recall, but the company would be notified promptly. They may find the contamination or we may find the contamination, or it may be referred to us by someone else. But in any event, the company will be immediately notified and, under the present arrangement, the product will be immediately removed from the market.

Q. Does the FDA approve labels for products under self-certification?

A. So far as I know the plan for self-certification does not include the review of labels. It does involve sanitary aspects, and composition of the products, primarily from the standpoint of assuring that the products meet the specifications set forth in the agreement. It does not go to the point of labeling approval for the product. We assume that when a firm is ready and willing to come into a self-certification program, they also have prepared themselves from the standpoint of insuring that their products are being labeled properly.

Questions Addressed to Mr. Goodrich

Q. You refrain from discussing with Mr. Hutt the philosophy and legalities of broadened factory inspection of food plants. Will you not address yourself to that specific question? Please, at least briefly describe the *Smith Canning* case and its implications, citations, etc.

A. The only reason that I refrained from discussing the philosophy is that my views have been set down very carefully in writing.

They are available in the FOOD DRUG COSMETIC LAW JOURNAL, and if any of you are sufficiently interested I will be glad to mail you a copy. But lest the point be around that I am not willing to discuss the issue, I can say very briefly that when the factory inspection amendment of 1953 was passed, there was a legislative history in the Senate Committee Report that went one way and a legislative history made on the floor of the house that went another. The authority was expressed at that time, just as it had been back in 1938 with the addition that inspection should be conducted to a reasonable extent, at a reasonable time, in a reasonable manner. An unreasonable number of reasonables but that was all that was added there. The only case on the books that deals with this at all is a food case called *U. S. v. Crescent-Kelvan Co.,* and it deals with the point in a dictum sort of a way, saying that the inspection authority covers all things in the plant. Nonetheless, when this legislation was on the floor of the House, views were expressed by the Chairman of the Committee and other sponsors that the inspection of certain records, formulas, and complaint files would not be reasonable in certain cases. This was during the debate. After that was over with, Mr. Crawford, then Commissioner of Food and Drugs, announced that we would not insist on access to those records that were covered by the debate if they were refused to us, but that we would continue to ask for such records in the course of inspection. Which leads me to another question here.

Q. Is the Food Industry obligated to turn over to inspectors written records such as formulas, complaint files and production records during a general inspection? If so by what authority? If not why do your inspectors ask for such? This leads me to another question.

Q. Present factory inspection is limited to sanitary practices of food plants. At least that's the general idea in present law. If this is substantially so, why do FDA inspectors regularly ask all sorts of questions not related to sanitation, adulteration, or filth. Is it FDA policy to instruct inspectors to ask a series of questions involving quality control, laboratory records, and formulas, just in the hope that they will get answers from unknowing company personnel? Why doesn't FDA instruct inspectors not to ask questions that are improper and outside the authority of present law? This would be real cooperation and evidence of mutual respect and trust.

A. Even in the Supreme Court cases decided last Fall, where the court held that it was a violation of a person's constitutional rights to inspect his establishment without a warrant, the Supreme Court

itself emphasized that most inspections were carried out and no doubt would continue to be carried out on a voluntary basis, making the access to these stronger enforcement procedures unnecessary. We are asking for this additional information because we regard it as essential to find out whether the companies are operating in compliance with law. No doubt we do not have, at this time, legislation before the Congress to extend the factory inspection authority, although it has been proposed by at least two presidents. This is a situation that will come up, continually, over the years and, as is the case with most ideas, its time will come. We are trying, meanwhile, to find out through voluntary cooperation, whether or not the firms are producing in full compliance. As I indicated in my statement extemporaneously, the going for an inspection warrant does offer us the possibility of putting some of these questions up to the judge in advance and asking him if he will put in the inspection authority the scope of the inspection. For that reason we have asked and instructed our field people to seek these warrants primarily from District Judges rather than from U. S. Commissioners. We have a feeling that if presented with some of these questions, in advance, Federal District Judges will be inclined to rule one way or another before the inspection takes place and then the company will be faced with a warrant in addition to the statute. Not a search warrant, I hasten to say, because we think this isn't the kind of case for a search warrant, which involves self-help and all of that. So our procedures call for obtaining an inspection warrant, which is somewhere between an inspection, without ever going to a magistrate, and the strong-arm search warrant.

Peter Hutt Comments

I have with me today the 1953 Press Release which the FDA issued upon the enactment of the present factory inspection authority. I think it might be useful if I simply read about its exact inspection authority and I quote three paragraphs which I think cover all the points that Mr. Goodrich made.

"Modern production and distribution are carried on to a large extent through the medium of written instruction and records. The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files and personnel files within the scope of the required inspections.

"FDA interprets this to mean that inspection of these records will be on a voluntary basis. Accordingly, inspectors have been instructed to ask permission to see such records or files whenever there is any

need or reason to examine them or to obtain information contained in them.

"The inspector may state reasons for asking to examine a particular record or file but will not otherwise press the owner, operator, or agent for permission to see it."

I believe, Mr. Goodrich, these questions reflect the standard field practice of FDA inspectors, first, not to explain that the records that they are asking to see are not required to be turned over under the statute. And, second, to go far beyond this statement, that inspectors will not otherwise press the owner, operator, etc., to see them. Could you comment on that?

Mr. Goodrich

Yes, I think that the press release says what I reported it to say; moreover, your own Harvard Law Review commented on this press release right after that by saying that the agency went too far in the press release, and since that time there have been opened up opportunities or avenues for litigating some of these close questions without a criminal action, that is by injunction, which is now available to enforce a factory inspection since the 1962 amendments, and the more recent inspection warrant procedure. So far as I know, it's a question of your emphasis on the "not pressing the point." They are asking the points. If the persons demur on those, they're not pressed further except to urge them to give it to them. By "urge" I mean as a part of voluntary compliance. I do recommend to all of you that you look at the Supreme Court's attitude toward this area of asking for this kind of inspection and what they anticipate would be the business community's reaction to it. I think they would be somewhat dismayed if they saw what was going on here.

Mr. Hutt

I don't think I need make any more point about the voluntary nature of the request for inspection records that are not required.

Questions Addressed to Mr. Burditt

Q. If there are no statutory provisions for GMP regulations for food, if the food is produced not under GMP but nevertheless is not adulterated or misbranded why is it subject to seizure?

A. First of all it seems to me that the original hypothesis of this question is wrong, at least in the FDA's view. The FDA takes the

position, which I think is probably correct, that section 701 clearly authorizes the promulgation of regulations for the efficient enforcement of the Act. And section 402(a)4, in very general terms of course, says that a food is adulterated if it has been prepared, packed or held under insanitary conditions. The real question is, what are insanitary conditions? And the *Smith Canning Co.* case, (U. S. v. 1,500 Cases Tomato Paste, 236 F. 2d 208; CA-7, 1956) that has been mentioned several times, in a dictum only, says that maybe the FDA should be trying to spell out a little bit what is meant by insanitary conditions. And I take it that it is the purpose of the food GMP regulations to spell out exactly what is meant by the words "insanitary conditions." Maybe I shouldn't be spelling out Mr. Goodrich's case for him, but I guess he probably figured it out anyway. Now if on that background the FDA does have authority to promulgate regulations and does have authority to spell out what is meant by insanitary conditions, you come to the next question.

Q. Suppose the GMP regulations require for example that two steps in a manufacturing procedure be carried out in two separate rooms. But some small plant doesn't have two separate rooms, so they have both steps of the procedure in the same room. There is clear violation of the GMP regulations for food. Yet the finished product is perfectly good as far as adulteration or misbranding is concerned. Should that be a violation of the act?

A. Obviously, that's a tough question. I personally would have a great deal of difficulty in saying that the food should be adulterated merely because some manufacturer did not have two operations in separate rooms. Of course there are many other examples that could be used. But I think you get the idea that the question is, suppose you don't comply with GMP regulations but do have the sanitary plant and do have a finished product that is not adulterated or misbranded? That's a test case we may sometime get, although I rather expect that the FDA would be reasonable in a circumstance like that, and would probably not bring such an action.

Mr. Barnard Comments

I think we and you and the Supreme Court are all agreed that we have to do a certain amount of relying on the good judgment of administrators and prosecutors in administering a law of this kind. When we talk about whether we would allege violation, if you please, on the basis of everything being in one room instead of two, we have to look a lot further than that. Let's take this example: — suppose

we had evidence to establish that everytime you handled raw fish and handled the finished smoked fish in the same room you produced fish with botulism or at least there is a very high likelihood that you would. Then I think we might get very seriously concerned if a man didn't have separate rooms for handling raw fish and finished smoked fish. On the other hand, as a purely technical requirement where there was no significant threat to the public health, then I think that the attitude might be quite different. And I think we ought to view all these questions in a little bit more realistic manner, with apologies, since I'm not a lawyer.

Mr. Hutt Comments

I'd like to defend the lawyers in that respect. As I understand the position, Mr. Barnard is saying that it's all right to have wide open regulations as long as they're administered in a wise and humane way. This is very well as long as you have a guarantee of wise and humane administrators. If the evil days should come, however, when an unwise prosecutor enters the scene or an unwise administrator, the industry would then be at the mercy of this man. And that is why we should have narrowly drawn regulations, narrowly drawn statutes, so that industry and government know exactly what are the rights and duties of each, and know exactly how far it is permissible and impermissible to go.

Mr. Barnard

I don't want to carry this too far, but just in reply I might point out two things: (1) he expresses amazingly little confidence in our system of justice. If the courts would permit the bringing about of the ruin of an industry because we have a coldhearted administrator, there is something more fundamentally wrong than just wide open regulations. (2) the English language or any other language I know of lacks the preciseness of mathematical symbols. It is impossible for you to write something and for me to write it and for us to agree in complete detail on precisely what it is intended to convey.

Mr. Hutt

There is one other little bit of background on GMP's that might simply be useful to consider. There is a great deal of legislative history in the 1962 Drug Amendments to the effect that the Drug GMP regulations are intended to be guidelines, and not to have the binding

force of law. The vast segments of the drug industry believe this to be the situation. As Mr. Goodrich will point out, it has not yet been tested in the courts.

Mr. Goodrich Comments

The situation with the GMP regulations was a matter of substantial controversy before this section became law. When it first was proposed by us, we proposed that regulations be promulgated through the public procedures of section 701 (e) & (f). The senate committee rejected that and provided that they would have prima facie effect. That is, each case be subject to contest. President Kennedy wrote to Senator Eastland objecting to this. The committee withdrew from that position and said that the regulations would not be subject to contest, case by case. The problem with the GMP regulations, we must all remember, is to give more definitive meaning to the general language of 402(a)(4) itself, that is, "prepared, packed or held under insanitary conditions, whereby the product may have been rendered injurious to health or contaminated with filth." That general language has been sustained in the Court of Appeals as laying out an adequate guideline for a criminal prosecution. Now we're trying to be specific here in terms of implementing that general language. And far from using imprecise language we hope to use language that all of us will understand.

Mr. Burditt

This is my question. Certainly I think we are all sympathetic with writing down as much as we can so that we know exactly what we're talking about and don't have to rely on the vicissitudes of individual administrators from time to time. But in this particular case, it seems to me we've got a further problem of the question of notice and opportunity for comment, hearing, etc. I'd like to hear Mr. Goodrich make a comment, if he would, on the availability of hearings and the FDA's intentions to allow a hearing if requested in regard to the food GMP regulations.

Mr. Goodrich

We haven't crossed that bridge, but we are proposing to issue these regulations as notices of proposed rule making. We have become convinced, through a lot of experience, that firms can better make a presentation in this kind of a regulatory setting in writing than anyone can coming down to a general legislative hearing. There was a

general legislative hearing soon after the enactment of the Hazardous Substances Labeling Act at the request of the Chemical Specialty Mfrs Assn (CSMA). It was not as satisfactory as the written presentation. Now, I am sure you know that the court held the year before last in the *Texaco* case that the public proceedings of section 4 with Administrative Procedure Act were an adequate opportunity for the presentations of views in this sort of a legislative operation and that the regulations promulgated after such a public proceeding were the equivalent of those published after a hearing in the *Federal Power* case.

Questions Addressed to Mr. Barnard

I have two related questions:

Q. Does FDA have the competence, in the field, to evaluate and enforce GMP in the many varied industries they must regulate?

Q. When industry periodically is subjected to inspection by individuals completely unfamiliar with their particular industry, are they likely to have confidence in the individual's ability to interpret GMP?

A. Well, as far as our confidence to develop intricate GMP's for a particular industry, the answer is we don't have it. I have made several public appeals to industry to come forward to offer us help as we get around to developing appendices in specific industries, and we have had a very encouraging number of offers of assistance. And in response to these, I have assured those who have offered, that we intend to call on the technological expertise available to us. As far as the attitude of the inspector is concerned I might say this much, the inspector is there to get the facts. He's not there to interpret GMP's. And when he goes there to get the facts and reports them back to his District office, such interpretation as may be required by this language we've been discussing, depending on the degree of specificity, will be done at some level other than the inspector level. And this brings me to a point that I'm fond of making in discussions like this, because I find it is widely misunderstood. The point is that the inspector doesn't have any authority to order someone in the food plant to do anything. Very frequently the attitude is taken that — "The inspector ordered me to do this, but he just didn't understand the situation." If the inspector says he thinks you ought to do something, take his advice for what it's worth and if it isn't worth a nickel don't take it. And if you have any concern, check with the people at the District level. But don't get excited because the inspector

happens to place a certain interpretation on something. His job is to get the facts, not to tell you how to run the plant.

Q. Will the GMP regulations provide a procedure for proposing amendments to reflect technological changes in the future?

A. As far as I know, we don't intend or contemplate providing a specific mechanism in the regulations for this purpose, but you have my absolute assurance that our ear is open at all times. We have the authority to amend the regulations, whenever, in our opinion, they ought to be amended.

Q. Where a food additive order specifies that the additive may be used in accordance with GMP, who makes the judgment as to what level of use constitutes GMP to provide the intended effect?

A. Well, I've indicated in the GMP regulations that we don't intend to get involved with the food additives question. The question as to who makes the judgment, I don't know whether he means who individually or whether he means the industry or the FDA. Usually you can determine what is customary industry practice with respect to the use of an additive.

Question Addressed to Mr. Hutt

Q. Since the Congressional Investigation Committees have made the 5th Amendment a clear admission of guilt in the eyes of the public, if food questions are not answered during an inspection by plant personnel, won't the plant be equally publicized as guilty?

A. My concern, of course, is that this will happen. This is the basic problem with the concept of recording inspection refusals. This is also the basic problem of asking for records that are not required by statute to be turned over without making it clear that they need not be turned over. It can amount to government by subtle coercion. Mr. Goodrich stated earlier that the reason for the list of factory inspection refusals was for record-keeping purposes. But in 1962 a list of inspection refusals was submitted to Congress. And it appeared in every newspaper across the country. There was no explanation that these were not violations of the law. There was no explanation as to what their meaning was. It was used basically to impugn industry's motives and capabilities, and this is the type of difficulty that we can get into with the inspection refusal list. It also raises a question, I think, whether a refusal to answer a question will give rise to an inspection warrant requiring the answering of that question. As Mr. Goodrich has pointed out there are two possible types of war-

rants. One would be a criminal warrant under rule 41 of the Federal rules of criminal procedure. And the other would he some kind of civil warrant that, frankly has not been invented yet, because the courts have not been required to issue it, but which seems to have been created by the Supreme Court in the two recent decisions. I would certainly hope that no court would say that refusal to answer a question is probable cause to believe that a violation of law has occurred. Therefore, refusal to answer a question should not be probable cause to issue a criminal warrant. I would expect, however, that it might well be sufficient to get a civil warrant of this new type I have just described which would allow for general inspection.

Questions Addressed to Mr. Kedzior

Q. Will self-compliance in food industry be accomplished in effect only if specific control data is periodically submitted?

A. Perhaps the questioner meant self-certification rather than self-compliance. The self-certification program is essentially an agreement between a company and the FDA concerning procedures the company will follow to insure that its product, when it leaves the plant for distribution to the consumer, is safe and complies with established standards. A firm entering into this program has demonstrated that its quality control practices are effective to insure that the end product will be safe. It will not be contaminated or harmful in any way. It is made under sanitary conditions. The control data will be part of their records. They are not required to submit control data periodically to us. But the control data is available for an inspector who may visit the plant periodically in making his inspection. However the firm does supply monthly information on those products which do not comply with the specifications and requirements in the agreement. But specific control data is not periodically submitted to FDA. It is available for FDA review in the course of inspections. Other self-compliance programs such as self-inspection programs or quality assurance programs, which a firm may undertake, are implemented on a strictly voluntary basis, with no formal agreement involving the FDA. When an inspection is made of such a plant, the firm should feel free to discuss their program with the inspector and even solicit his comments for improvements in their program. But this is a voluntary approach on their part. We encourage firms to undertake such a program on their own initiative and we will assist them in any way we can.

Q. Although the FDA is under pressure to complete an inspection in the shortest possible time, a great service is provided by the inspector who takes sufficient time to teach those who accompany him about inspection techniques. Will inspectors continue to provide this educational service under the surveillance-type, partial-inspection program?

A. I would say that where an inspector has performed such a service to management, where he has taken the time to explain what he is finding, etc. I think he is doing a very fine job, although he might be called down by his supervisor for not getting the job done quicker. I would expect that he will continue to do the same thing under the partial-inspection type program. I don't think there would be any change. What will happen is that there may be fewer complete inspections. In the partial inspection program he is assigned to cover specific problem areas. If he finds everything satisfactory, he will not continue the inspection into other areas at this particular time. So that an inspection would take less total time than it did before. But when he finds problems he will go all the way.

Questions Addressed to Mr. Goodrich

Q. Will GMP regulations apply to meat packing and processing establishments? If so who will enforce them?

A. USDA has had such rules for a long, long time dealing with such minutia as stainless steel tops, and other things of that sort and they are enforcing them. There will be no change.

Q. Food plants which produce meat products are regularly inspected by USDA. If the same plant also produces non-meat products, does the USDA extend its purview to these products, or is the FDA charged with inspection in connection with these products? How do the two agencies co-ordinate on inspections and on regulations under the Fair Packaging and Labeling Act?

A. The lines of demarcation between meat and meat-food products and other products are intricate indeed. These have been announced by the meat inspection service of USDA. Where they have in-plant jurisdiction over all products we do not go into the plants. Where a plant makes both, inspected products and non-inspected products, both have jurisdiction. We have a working agreement with the inspection service to avoid difficulties. In the case of the Fair Packaging and Labeling Act, meat and poultry products were exempted by the Congress on the grounds that there was already

adequate authority in those inspection laws to provide the kind of packaging and labeling controls that were being sought for the products.

Mr. Barnard Comments

Mr. Goodrich, the group might be interested to know however, that we have been maintaining very close liaison with Agriculture on a number of meat labeling problems. In general, the USDA is going in the direction of requiring essential compliance with the Fair Packaging and Labeling Act with respect to meat and poultry products even though they are exempted.

Questions Addressed to Mr. Barnard

Q. Certain segments of the food industry are covered by comprehensive inspection programs by other governmental agencies such as the USDA. Isn't there a great duplication of regulations covering the food industry? Why should the FDA take over a function that is being covered by another agency?

A. Well, I think that's been largely answered insofar as mandatory inspection is concerned. There's only a limited duplication and the FDA has no intention or power to take it over. The problem is a little bit more difficult when we get into so-called voluntary inspection services like the USDA fruit and vegetable grading services where they provide, for a free, in-plant inspection. But there's nothing here that precludes FDA jurisdiction. So that there is duplication here. We are working closely with USDA on the GMP's for example, working out regulatory problems. We don't precipitate legal action involving products which have been or may have been produced under the USDA service without coordinating the problems with them first. This is not an area that is by any means totally free of overlapping. Much the same is true in the case of the Public Health Service with its so-called advisory regulations—recommended codes and ordinances. And I am pleased to advise you that there has been formed a top level inter-departmental committee among Health, Education and Welfare (HEW), Agriculture, and Interior for the purpose of addressing itself to a more orderly scheme for joint planning and joint administration of these overlapping responsibilities.

Q. Is it intended that proof of adherence to GMP guidelines will require inspection of records, recipes, quality data, etc?

A. We don't feel that the burden is on the man to prove that he is in compliance. The answer to the question is essentially no.

Q. Has or does FDA plan to consult with the states concerning the development of GMP's for the food industry?

A. I apologize most humbly. That is something I should have mentioned directly at one point or another. The answer is very definitely yes. We have been working with the states on some of them. We plan to try many of them by some of the states that are directly involved for their participation before we issue them. We are keeping the states well informed on this.

Question to Mr. Burditt

Q. Could we have some discussion of the 7th Circuit case that Mr. Goodrich feels supports the argument that the proposed GMP guidelines will have the force of law?

A. I believe that's probably the *Smith Canning Co.* case. That case was a seizure of tomato paste based on FDA's position that the plant was insanitary. In other words a violation of section 402(a)4. You know under (a) 4, the finished product is adulterated if it's made under insanitary conditions even though the product itself, on analysis or anything else, turns out to be unadulterated as far as any contamination is concerned. And in that case the court wrestled with the problem that we're really wrestling with in GMP. Are we better off either in terms of FDA, or consumers, or industry, to have general terms like "manufactured under insanitary conditions" which is the wording of the statute? Or are we better off to have what is meant by "insanitary conditions" spelled out in the terms of GMP regulations? And the court in that case, purely by way of dictum, merely said maybe this is an area that FDA ought to take a look at and ought to consider being more specific about, since the statute is so general.

Mr. Goodrich Comments

I would prefer that everyone who has a concern here look at the case itself, to evaluate it. It is a 7th Circuit case. Its title is *U. S. v. 1500 Cases of Tomato Paste.* Smith Canning Co. was the shipper. The issue was whether or not the product had been made under insanitary conditions. In this case, the court said that in the absence of regulations, they would, in applying (a)4, apply the average conditions of cleanliness and sanitation in plants throughout the U. S. The court further said that, if we wanted to have a different rule than the average, if we wanted to improve the conditions in this case—to have

screens on the windows to keep the flies out, instead of to let them out as claimed by the company as the purpose of not having any screens —we should promulgate regulations and they would likely receive the support of the court. Very significantly, in that case we did have a regulation on mold count of 40, making tomatoes adulterated, a purely administrative rule, and the court gave that the force and effect of law. So I don't take the case as being a dictum. But I yield to any lawyer here who wants to have a different view of it.

Question Addressed to Mr. Goodrich

Q. Why is FDA reluctant or unwilling to give duplicate samples taken during inspection so that the inspected plant can evaluate the samples also? This is particularly an evaluation problem in the case of "inprocess Samples."

A. There is no reluctance to give those samples. As a matter of fact, we encourage the companies, who are inspected, to send a man along with us and to take samples at the same time we take them. If they don't do that, portions of our samples are available.

Questions Addressed to Mr. Hutt

Q. Recently, several food producers have requested inspection privileges of the plants of their suppliers. Is not this a duplication of the FDA effort?

A. Yes it is clearly a duplication.

Q. If all customers of the firm would request inspection privileges where would this lead to?

A. I guess the easy answer is that it would lead to a lot of inspections. I'm afraid from a legal viewpoint there is very little to be said on this. This would be a matter of policy. It is a duplication of effort. Unless there are extraordinary circumstances, I can think of no reason for it.

Questions Addressed to Mr. Goodrich

Q. When advisory opinions are given, or when GMP regulations are prepared, is an effort made to make sure that the FDA as an agency is willing to *insist* on compliance by way of court action if necessary?

A. Of course we're prepared to insist on compliance but we're not prepared to say that every little instance is a basis for regulatory

action. Nor are we prepared to withhold an advisory opinion, asked in good faith, simply because at the moment we're not prepared to take that issue into court. For example, in connection with the efficacy review of a large number of new drugs, we have expressed our views on the status of a lot of those products, although those products are now under review at the National Research Council. We have an agreement with them not to take any regulatory action, until we get an opinion from them. We don't feel we should withhold advisory opinions during that time. Nor do we feel that if we put out a GMP we should restrict the coverage to those things that would be the immediate ground for bringing a criminal or civil action.

Q. I understand Dr. Daubert to say General Foods did not give the FDA formulas. Why do inspectors ask for more in a general inspection?

A. We had an agreement with General Foods over exactly what would be told to us and the conclusion was that we had adequate information from them to carry out this mutually agreeable system. The inspectors are asking for more detailed formula information in the inspection to try to find out whether the products are being produced in compliance. And if the company is satisfied to give just the composition, without the quantitative amount, we will be very happy to receive it.

Q. If a company refuses to produce complaint files, general quality control records, or the like to an inspector who has requested such documents, will FDA seek an inspection warrant for such information?

A. We've only started in the inspection warrant business now. The instructions out to the field are that where a firm refuses inspection, the inspectors are to confer with us on whether we think it is a substantial enough violation to call for an inspection warrant, and then to proceed, on instructions, through the U. S. Attorney General and the U. S. District Judge for the warrant. There will be some cases in which complaint file and quality control records might be very vital, but certainly this would not nearly reach that point where we've not even had a single decision under the whole concept of inspection warrant. We may be wrong that the Supreme Court meant what it said and that we could get a warrant without really complying with rule 41. But we think it's worth presenting to the U. S. District Judges with the authority of the recent Supreme Court cases to test the inspection authority. **[The End]**

Fair Hearing in Administrative Rule-Making:

A Recent Experience Under the Federal Food, Drug and Cosmetic and Fair Packaging and Labeling Acts

By WESLEY E. FORTE

The Following Article Is Reprinted from the *Duke Law Journal.** Mr. Forte, a Member of the Pennsylvania Bar, Is an Attorney with the Borden Company.

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 stan-

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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] See footnote 2 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 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 state-

(Continued on next page.)

dards for the labeling of consumer 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]

(Footnote 4 continued.)
ment 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. § 4, 15 U. S. C. § 1453 (Supp. II, 1967). The Act also authorized certain discretionary regulations. § 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 regulations 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] See footnote 8 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 hearing deserves detailed review because it is apparently a significant change in the procedures followed by the FDA. Since few litigated

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

[13] See footnote 8.

[14] See, for example, Burditt, "Fair Packaging and Labeling—The Cost to Consumers," 22 FOOD DRUG COSMETIC LAW JOURNAL 542, 545-46 (1967).

[15] See, for example, *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, cited at footnote 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* (D. D. C. April 1950), reported in V. Kleinfeld & C. Dunn, *Federal Food, Drug and Cosmetic Act—Judicial and Administrative Record*

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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 Foreign 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 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]

(Footnote 20 continued.)

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 below.

[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 footnote 8.

[23] H. R. Rep. No. 2139, 75th Cong., 3d Sess. (1938) (reprinted in C. Dunn, cited at footnote 21, at 815, 824).

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 Commission 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

[24] See footnote 8.
[25] 301 U. S. 292 (1937).
[26] See footnote 25 at 300.
[27] See footnote 25 at 302-03.

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]

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]

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[28] See C. Dunn, cited at footnote 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. See footnote 25 at 746.

[29] See H. R. Rep. No. 2139, cited at footnote 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, cited at footnote 21, at 810. Therefore, 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 COSMETIC LAW QUARTERLY 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 below. 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).

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 principles —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 chocolate 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

[33] See *Attorney General's Manual on the Administrative Procedure Act* 32-33 (1947); Austern, "The Formulation of Mandatory Food Standards," 2 FOOD DRUG COSMETIC LAW QUARTERLY 532, 574 (1947); Markel, "Reviewing Food Standards," 6 FOOD DRUG COSMETIC LAW JOURNAL 191, 201 (1951); "Developments in the Law—The Federal Food, Drug and Cosmetic Act," 67 *Harvard Law Review* 632, 666-68 (1954).

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

[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. See footnote 34 at 574.

[36] See footnote 34.

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 FDA 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 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

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[37] *Cook Chocolate Co. v. Miller* (D. D.C. April 1950), reported in V. Kleinfeld & C. Dunn, cited at footnote 20, at 251.

[38] See footnote 37 at 252.

[39] See Levine, cited at footnote 30, at 172.

[40] See footnote 39 at 180.

[41] 83 Cong. Rec. 7776 (1938) (remarks of Representative Lea).

[42] See footnote 41 (emphasis added).

[43] See footnote 41. See also Salthe, "Food Standard Making—What Did Congress Intend?," 6 FOOD DRUG COSMETIC LAW JOURNAL 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."

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* 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 hear-

[44] See text accompanying notes 23-33 cited above.

[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 *Harvard Law Review* 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 administrative determination. Austern, "Section 403(g) Revisited," 6 FOOD DRUG COSMETIC LAW JOURNAL 181, 183 (1951).

[46] *Cook Chocolate Co. v. Miller* (D. D.C. April 1950), reported in V. Kleinfeld & C. Dunn, cited at footnote 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 cited above. 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 *Harvard Law Review* 632, 668 (1954).

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

ings 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, 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 if the grounds in the petition are reasonable, the hearing should section 507 of the Federal Food, Drug and Cosmetic Act.[52] Among

[48] See *Cook Chocolate Co. v. Miller* (D.D.C. April 1950), reported in V. Kleinfeld & C. Dunn, cited at footnote 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, cited at footnote 30, at 175-76.

[49] Cf. Levine, cited at footnote 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 judicial 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); compare 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, for example, Markel, cited at footnote 33, at 191. See also Goodrich, "Patchwork on a Crazy Quilt of Administrative Procedures," 10 FOOD DRUG COSMETIC LAW JOURNAL 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 (1953). See also Markel, "Proposed Simplification of Food Standards Procedures," 8 FOOD DRUG COSMETIC LAW JOURNAL 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 COSMETIC LAW JOURNAL 191, 202-03 (1951).

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 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 FDA 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

[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); Markel, "Proposed Simplification of Food Standards Procedures," 8 FOOD DRUG COSMETIC LAW JOURNAL 227, 234 (1953).

[55] See S. Rep. No. 1060, cited at footnote 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, cited at footnote 54, at 12.

[58] See Markel, "Proposed Simplification of Food Standards Procedures," 8 FOOD DRUG COSMETIC LAW JOURNAL 227, 235-36 (1953).

[59] See S. Rep. No. 1060, cited at footnote 54.

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 Secretary 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]

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

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

[62] See *Hearings on H.R.* 5055, cited at footnote 54, at 7.

[63] This letter is part of S. Rep. No. 1060, cited at footnote 54.

[64] See S. Rep. No. 1060, cited at footnote 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).

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 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, although 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

[66] See footnote 41.

[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] See footnote 70 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.

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.

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

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[73] See footnote 72 at 285-86.

[74] See footnote 72 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, cited at footnote 54; Markel, "Reviewing Food Standards," 6 Food Drug Cosmetic Law Journal 191, 202 (1951).

[79] Compare Federal Food, Drug and Cosmetic Act § 507, 21 U. S. C. § 357 (1964), with footnote 78 § 701(e)(2), 21 U. S. C. § 371(e)(2) (1964).

him by the sponsors of the Hale Amendments.[80] In short, the 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

[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 COSMETIC LAW JOURNAL 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.

[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 cited above. 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 [that is, 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. § 701, 21 U. S. C. § 371 (1964); *Federal Security Adm'r v. Quaker Oats Co.*, 318 U. S. 218 (1943). See also Austern, "The Formulation of Mandatory Food Standards," 2 FOOD DRUG COSMETIC LAW QUARTERLY 532, 582-89 (1947).

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 expected 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

[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, cited at footnote 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).

[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), affirmed under the name of *Libby McNeill & Libby 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, cited at footnote 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.

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 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

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[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.

[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, cited at footnote 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 cited above.

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 depending 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.

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[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 cited above.

[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.

[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 cited above.

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]

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

[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 accompanying notes 67-76 cited above); and *Cook Chocolate Co. v. Miller,* 72 F. Supp. 573 (D. D. C. 1947) (reviewed at text accompanying notes 34-49 cited above). 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 Administrative Procedure Act § 4(b)(3)(A), 5 U. S. C. § 553(b)(3)(A) (Supp. II, 1967).

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 name was unreasonable.[98] Reasoning that the actual name of the corporation was required by the statute, the FDA rejected all re-

[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 cited above.

[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."

quests 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 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

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[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).

[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."

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 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

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[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." See footnote 103 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. See footnote 103.

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

[106] See footnote 105.

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 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]

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[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, for example, Austern, "The Future of Mandatory Food Standards," 9 Food Drug Cosmetic Law Journal 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 Cosmetic Law Journal 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 cited above.

[110] Arguably, the Commissioner erred on at least one other objection. The objector challenged the requirement that packages bear the words "net

(Continued on next page.)

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-

(Footnote 110 continued.)
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, for example, 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 § 1.3(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.

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

(Continued on next page.)

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

(Footnote 110 continued.)

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, cited at footnote 6-7.

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

[113] See footnote 112 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. See footnote 112.

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

[116] A collateral problem under the Fair Packaging and Labeling Act regulations raised vestiges of *Cook Chocolate*

(Continued on next page.)

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]

(Footnote 116 continued.)
Co. v. Miller. See text accompanying notes 34-39 cited above. 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 rule-making 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

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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. **[The End]**

(Footnote 117 continued.)
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." § 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 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 cited above. 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."

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