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ood·Drug·Cosmetic Law JOURNAL

1961 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc.— Papers from Industry and Consumer Sessions and Panel Discussion

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD 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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REPORTS

TO THE READER

This issue of the FOOD DRUG COSMETIC LAW JOURNAL contains most of the concluding papers of the 1961 Joint National Conference of Food and Drug Administration and The Food Law Institute which was held in the auditorium of the United States Department of Health, Education and Welfare, Washington, D. C., on November 27 and 28, 1961. The December, 1961, JOURNAL contained the addresses presented at the FDA session on November 27. This issue includes the speeches of the industry session of November 27, the consumer session of November 28 and the panel discussion of questions submitted to the conference.

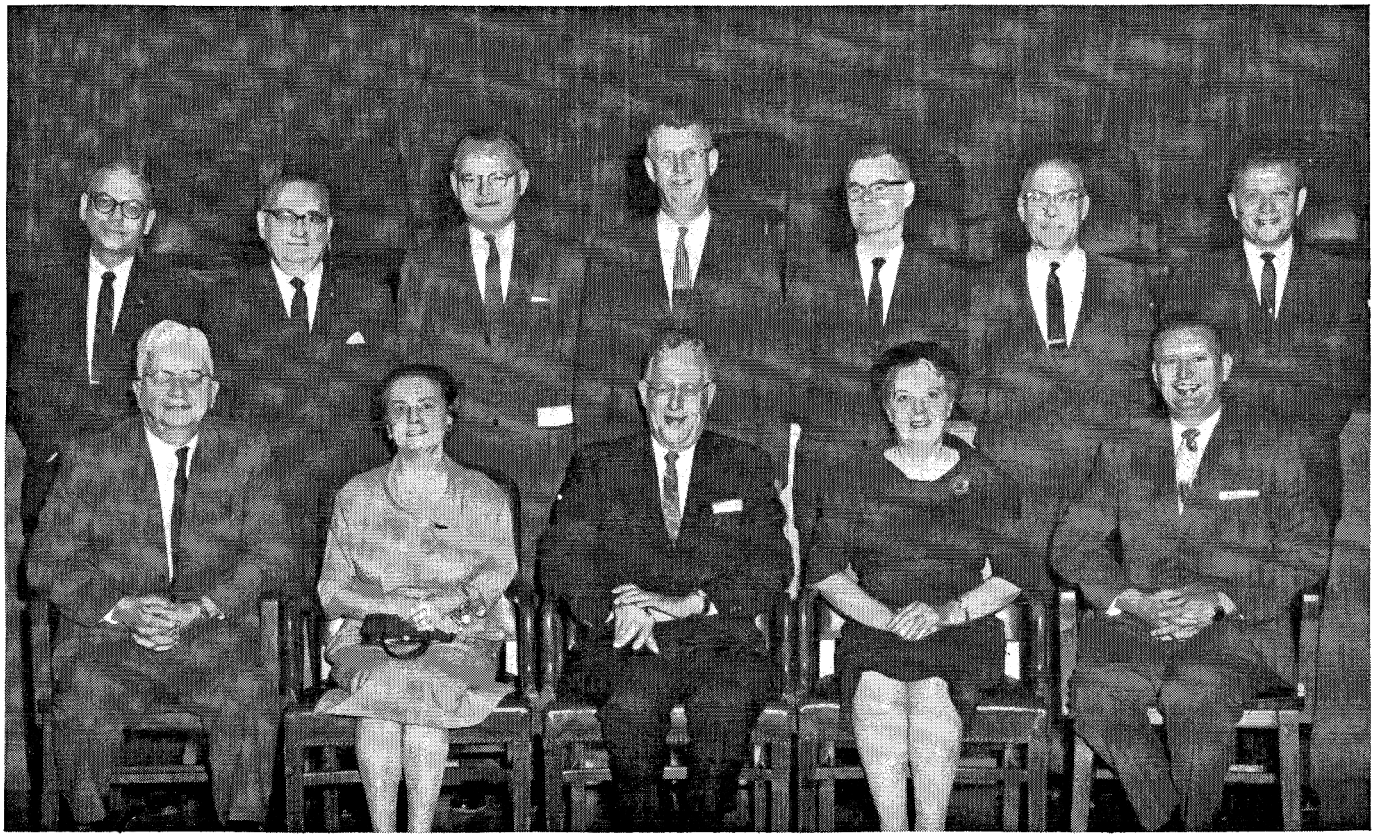
These two issues of the JOURNAL comprise a complete record of the conference with one exception. Unfortunately there is no available copy of the address of *William Curtis Adams, M. D.*, President of the American Association of Poison Control Centers, who spoke at the Consumer session. The title of Dr. Adams' speech was "The Work of the Poison Control Centers."

Dr. Austin Smith, President of Pharmaceutical Manufacturers Association moderated the industry session and gave the introductory statement. It was followed by the first of the discussion papers. *Dr. S. F. Kern,* Executive Director Control Division, Eli Lilly and Company explained the legal problems that confront the researcher and the difficulty he has in keeping abreast with the changes in requirements under prevailing rules, in particular those demanded by a new drug application.

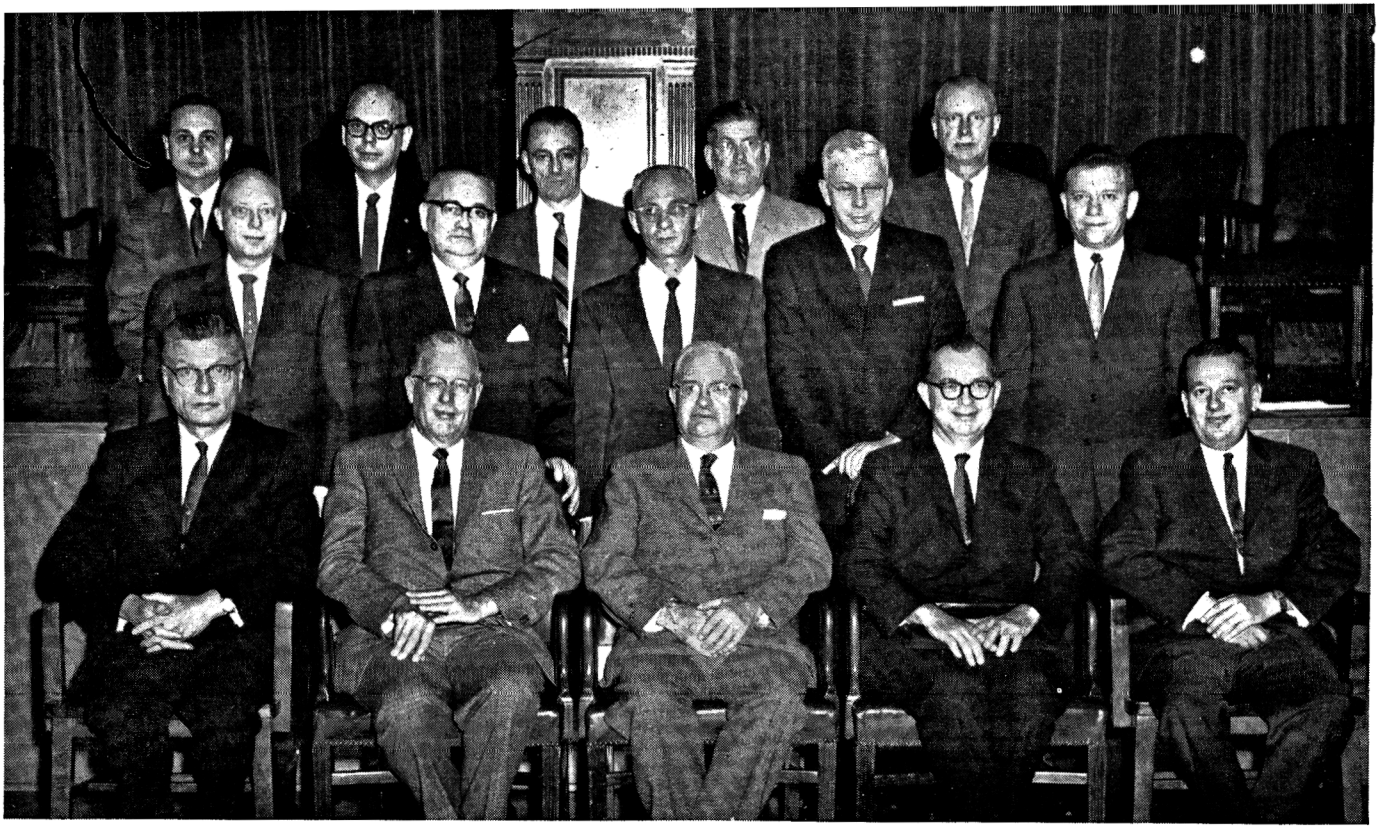
A discussion of the Kefauver-Celler Bills, which were an outgrowth of Congressional hearings is presented by *Raymond D. McMurray.* He calls these bills a "three-pronged attack" amending the Sherman Act, the Food, Drug, and Cosmetic Act and the patent laws. It is his contention that this legislation indicts the industry, imposes impossible burdens upon the Secretary of Health, Education and Welfare and the FDA, and does violence to the patent system. The author is Secretary and General Counsel of Hoffman-La Roche, Inc.

A continuation of the discussion of the Kefauver-Celler bills is found in the article by *Bernard L. Oser, Ph. D.* He makes special reference to the proposed legislation to allow the inspection of laboratories. He says that to single out commercial laboratories for this inspection is discriminatory as there are many other institutions and individuals who have a role in evaluating the efficiency, safety, quality and potency of drugs. Dr. Oser assures his audience that the drug industry is desirous of supporting any legislation that promotes public health and welfare but insists that it is essential that the privacy in relations between a consulting laboratory and its client remains. He

(Continued on page 6.)



Participants in the 1961 Joint National Conference of the FDA-FLI are shown in the above photograph. In the front row, from left to right, are Bradshaw Mintener, Edith H. Sherrard, Franklin M. Depew, Dr. Persia Campbell and Dr. William Curtis Adams. In the back row are Dr. John A. Zapp, Dr. Bernard L. Oser, J. Kenneth Kirk, Franklin D Clark, W. B. Rankin, Robert S. Roe and Dr. Daniel Banes.



Also participating in the 1961 Joint National Conference of FDA-FLI were the following (seated, from left to right): Kenneth E. Mulford, Franklin M. Depew, John L. Harvey, Dr. Stanley F. Kern and William W. Goodrich. In the middle row are James R. Cribbett, Dr. Bernard L. Oser, Dr. Henry Fischbach, Dr. Frank W. Wiley and Dr. Daniel Banes. Raymond D. McMurray, Dr. John A. Zapp, Eugene A. Chase, Dr. E. William Ligon, Jr. and Dr. Glenn G. Slocum are in the last row.

(Continued from page 3.)

is the President of Food Drug Research Laboratories, Incorporated.

Kenneth E. Mulford, Assistant to the Executive Vice President of Atlas Chemical Industries, Incorporated, states that scientifically and technologically great advances have been made in the food and drug industries. There is new legislation to govern the use of these discoveries. The only problems remaining, states the author, are those of compliance with and effective administration of the laws. The new Citizens Advisory Committee, in reviewing the current status of the FDA, may well present some solutions to the problems.

As a result of Public Law 85-929, passed September 6, 1958, the flexible packaging industry has found itself directly concerned with the legal and safety aspects of food. In his address to the conference members, *Adolf Miller,* the Vice President, Research and Development, Milprint, Incorporated, reviews the situation as his industry sees it.

"I see no insurmountable problems in the food color additive field, but I think that an active program is necessary for many of us to bring about a full and rapid compliance with the law." This is the conclusion reached by *Eugene A. Chase,* Counsel, Sterwin Chemicals Incorporated after reporting on the current status of food color additives and making suggestions as to what should be done in the coming years.

The chairman of the Department of Economics, Queens College, *Dr. Persia Campbell,* presented an excellent and well researched paper on the problems the consumer encounters. The opinion presented is that it is not that there is a need for a mass-communication program to inform the consumer of the "image" and the industry position, but a need to take into account the underlying problem which is one of attitudes and relationships and a recognition of both the function of the consumer in the economy and of the function and responsibility of industry.

To bring this conference to a close, there was a panel discussion of the questions submitted to the conference. This panel was moderated by *Mr. Franklin Depew,* President of the Food Law Institute. Representing the Food and Drug Administration were *Dr. Daniel Banes, Franklin D. Clark, William W. Goodrich, J. Kenneth Kirk, Winton B. Rankin* and *Robert S. Roe.* The consumer was represented by *Dr. William Curtis Adams* and *Dr. Persia Campbell. Raymond D. McMurray, Kenneth E. Mulford, Dr. Bernard L. Oser* and *Dr. John A. Zapp* represented industry and science.

In the February issue will be found the remainder of the conference papers which are briefly reviewed here.

In the article on the Federal Hazardous Substances Labeling Act, the author, *Dr. John A. Zapp* reviews the legislative history of the Act and shows that industry has played an active role long before this particular labeling act was passed. He feels that now the industry has been relegated from the role of cooperator to that of the regulated. Dr. Zapp, Director, Haskell Laboratory for Toxicological and Industrial Medicine, E. I. du Pont de Nemours and Company, explains his feeling on this topic and suggests how the situation might be improved.

Dr. S. Allan Lough, Assistant Director for Radiological Physics, Division of Biology and Medicine, Atomic Energy Commission, explains the situation which has presented itself as a result of the explosion of nuclear weapons. Of the many problems produced, the fallout of strontium 90 and cesium 137 are of chief dietary concern. Dr. Lough discusses those problems and tells what remedial measures are being attempted.

The last of the papers presented at the conference was that of *Edith H. Sherrard,* staff associate, Social and Economic Issues, American Association of University Women. Mrs. Sherrard explained what projects were presently in action as a result of the efforts of her organization and asks the aid of both government and industry in their effort.

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Legal Problems of the Drug Research Director

By DR. S. F. KERN

Dr. Kern Is Executive Director, Control Division, Eli Lilly and Company. In This Speech, He Discusses the Changes in Interpretation of Regulations and Statutes Which Affect the Industry.

MY OBLIGATIONS include assuring the management of my company (1) that the products which we produce and market are safe and efficacious for their intended purposes, (2) that they will meet applicable regulatory requirements, and (3) that they will be acceptable to the consuming public.

At first look, these three requirements appear separate and distinct. More careful consideration of them, however, brings one to the realization that if they are not one, they should be. This, of course, would be ideal; but, I am afraid this is not the fact.

In my job, I am called on to interpret governmental regulations and help translate them into sound experimental design. It is not reasonable to expect some 1,400 people in the research, development and control areas of the company to be familiar with all the laws and regulations affecting their activities. It is interesting to note that on the federal level alone, at least five departments play some role in the regulation of ingredients which can broadly be thought of as food additives or drugs. They are: the Department of Health, Education,

and Welfare; the Department of Agriculture; the Department of Interior; the Department of the Treasury; and the Department of Commerce. Within these departments, the number of separate divisions and branches are almost innumerable with inevitable conflicts of statutes, regulations and interpretations. The conflicts exist not only among departments, divisions and branches, but also within branches depending apparently upon the time and temperature.

Now just what are some of these conflicts or dilemmas which exist at present and plague anyone faced with the problem of directing scientific effort toward the discovery of new products or new uses for old products?

The first point that causes no end of trouble is the fact that things do not stay constant. There is an ever-changing attitude on the need for regulations and their status at any moment.

When the basic Food and Drug Act of 1938 was enacted, the kind of drugs and food additives which were marketed were greatly different from those being developed and marketed today. The intent of Congress when the 1938 legislation was enacted was to cope with the problems as Congress recognized them at that time. But today we find that Congress is retroactively granted omniscience and prescience to have foreseen all the possible problems which have arisen during the last 20 some years. I always read with a little chuckle the preamble: "It is clearly evident that Congress had anticipated . . . and provided . . ."

It suffices to say that there have been reinterpretations of regulations and statutes because of: (1) the change in our knowledge, (2) the change in the kind of products we are producing, and (3) the change in the political evironment.

Anyone who is charged with the obligation of directing research efforts toward meeting these regulatory requirements must face the fact that they are ever changing, and it is not sufficient to attempt an interpretation of the regulations as they exist today without considering what might be the regulations a year or two years hence when the products which are now being investigated may be ready for market.

It is not that I am opposed to progress or increasing the safety of products. I am concerned over the manner in which these changes take place. Apparently during the investigation of one new drug a particular study or control was found useful in assuring the safety

and/or "efficacy" of this preparation; hence, this study or control was incorporated into the new drug application of Company A.

This is information which the personnel of the Food and Drug Administration now has. It is not, however, public information.

In reviewing the next new drug application, the reviewers of the Food and Drug Administration, being only human, generalize the findings of the previous new drug application and ask whether these findings should not be made a requirement of this second new drug application, with the result that Company B needs then to go back and do work to prove that the situation which was present in Company A's application is not present in their application. This, Company B may be asked to do without really knowing what Company A said or why they said it.

I am sure those of you who are familiar with the changes that have taken place in new drug requirements over the last 25 years appreciate what I am saying.

I took the opportunity to look at a new drug application submitted in 1940 and compared it to one submitted in 1950 and one in 1960. As far as the legislation on new drugs is concerned, there has been no basic change over that 20-year period. However, the thickness of the new drug application went from six pages to 60 pages to nearly 600 pages. This must be regarded as evidence of a change in interpretation of regulatory requirements during the 20-year period.

Starting about three years ago, we began investigation of a product which appeared to have some useful qualities. We certainly were aware that there would undoubtedly be food additives legislation and had some ideas as to what its content might be. We had a pretty good idea of the feelings of the Food and Drug Administration and started our investigational efforts along that line.

Three years later, the two-year rat and dog studies which were only talked about then are completed. All of the other tests which we felt would be adequate to sustain the utility and safety of the product have been completed and the food additives petition submitted.

The letter denying the completeness of the application and making it unacceptable for filing consists of two pages of considerations which the Food and Drug Administration feels need now be considered before the application can be filed. I am quite sure that few if any of these questions would have been asked three years ago. I

do not wish to leave the impression that these are necessarily bad or unnecessary requirements, but the changes which take place in a period of legislative activity create problems which are almost insurmountable—especially when the changing requirements involve tests which take years to accomplish. In that period of time, there can be further changes requiring further delays and expense.

Even without this changing climate which we face, what other elements contribute to the situation as we see it today?

Let us assume that a company discovers a chemical compound which produces a physiological response in a farm animal. This physiological activity automatically makes the compound a new drug. In reviewing the requirement for such a product, one would expect that this product would be considered by the Veterinary Branch of the Bureau of Medicine.

If, however, it is decided that a practical method of administration of this drug is by the oral route—such as putting it in drinking water or in animals' feed—it would become a feed additive. It would then be subject to another set of laws and regulations but not exempt from the requirements of the new drug section. If the product is administered by intramuscular, intravenous, or intrasinus routes or by oral tablets or powders, it is not a feed additive.

Now what are some of the consequences? If it is a feed additive, the cancer clause applies. If it is not, the cancer clause does not apply.

Section 3.7 of the regulations issued on November 30, 1948, contained the following statement:

> In considering a new-drug application for a product intended to effect physiological changes in farm animals, the Federal Security Agency will regard the absence of satisfactory evidence showing the meat or other food obtained from animals fed the drug to be entirely free at the time of marketing from any poisonous or deleterious ingredient resulting therefrom as grounds for refusal to make the application effective.

This regulation became a requirement for zero tolerance for products intended to effect physiological changes in farm animals. With the passage of the Food Additives Amendment, this regulation disappeared and now the determination on a new drug application as to whether or not the product should be considered under the Food Additives Amendment becomes a judgment for the Veterinary Branch. Such a decision is made after the new drug application has been submitted and is based on the possible residues which might exist

under the conditions specified, the data on withdrawal, or the toxicology of the product. This is an example of the effect that legislation in one area has on the regulations which are in effect in another area.

Within the last six months, a new drug application has been made effective providing for use of Diethylstilbestrol implants in beef animals. At the same time, a feed manufacturer cannot get a clearance to put Diethylstilbestrol into a new feed or to change plant locations.

In determining residues, the analytical chemist is faced with the definition of zero. Although the Food and Drug Administration has said that zero can only be defined in terms of an analytical procedure, nothing appears in the regulations defining zero in terms of the sensitivity of the method for each food additive. Further, no consensus is available as to what represents the sensitivity of a method. Is it the level at which a statistically significant difference exists between the control and the test sample? If so, how statistically significant must it be—90 per cent, 95 per cent, or 99.7 per cent level of confidence?

Now this needs to be explained to the research worker, the chemist, the pharmacologist, the veterinarian and the animal nutritionist so he may continue with his work in directing the development of a product. Obviously he is confused, and the best we can do is to tell him to go ahead and carry out his work and do everything necessary to cover the situation regardless of which way the application goes. Much of the work, we realize, will not be necessary to prove safety and efficacy—but most likely it will be needed to meet all of the regulatory requirements.

Later in the development of our new product, we find that it is useful in combination with another drug: for example, a certified antibiotic. Now it becomes necessary to do all of the testing over because there is a remote possibility that one of the two drugs might change the action of the other.

It can be argued that we just don't know whether or not these drugs in combinations will really affect each other; hence, we must test them. Now these considerations arise only if the two active principles are placed in combination in a marketed preparation. If they are sold separately but fed simultaneously, there is no jurisdiction.

If the product is a drug, efficacy is not a statutory requirement, but it does get in through the back door by virtue of the interpretation.

Here is one of those time and temperature situations—a product cannot be judged safe if it is not efficacious.

If on the other hand, the product is a feed additive, utility or usefulness must be demonstrated. In combination with a certifiable antibiotic regardless of whether it is a drug only or a drug and feed additive, efficacy must be shown; and the submission now is made to the Certified Antibiotics Section rather than the New Drug Section. If the product alone and in combination is to be considered, separate applications to each group are required as well as to the food additives group.

There also exist conflicts of statute which make it difficult to direct research activities. We find, for example, that a product which can be used both as a feed additive to produce a certain effect and also as a pesticide is regulated under two opposed statutes. Under the food additive statute, the Delaney anticancer clause takes effect; and if the product is a carcinogen, its use is prohibited. On the other hand, if the material is to be used as a pesticide, it comes under Regulation 120.5 and is permitted to be used as long as the residue remaining in the edible product is zero. In other words, it is permitted to be used based on a zero tolerance. It will take legislation to achieve some kind of uniformity in these cases.

In the Food and Drug Administration's consideration of applications under the new drug provisions, certifiable antibiotic regulations, or the food additives regulations, there are differences as to required times of official review by the Administration. Under the new drug provisions, action, whether favorable or not, must be taken 60 days from receipt of the application by the Food and Drug Administration. This statutory limitation provides further that if action is not taken within this time, an application automatically becomes effective. Under the certifiable antibiotic regulations there is no mandatory time for consideration of an application. For the most part the Food and Drug Administration Division of Antibiotics attempts, through their own volition, to take action on an application within 60 days. The food additive regulations specify different times (15 or 30 days from receipt) for initial review of a petition depending upon whether or not the proposed additive is also a new drug. However, these stipulated times constitute only attainment goals since there are no penalty provisions if action is not taken within the specified times.

The use of color additives in drugs is recognized as contributing to safety, efficacy and customer acceptance. The responsible members of the industry are faced with the problem, therefore, of assuring themselves that adequate colors will continue to be available. How can this be accomplished? At present, there are no regulations which define many provisions of the act in regard to the assignment of tolerances based on necessity. How then can a research effort be conducted with the assurance that an economic good which might result from such an investigation will in fact be granted a company or companies sponsoring such a program? Will each product containing color need to be subjected to a separate color additives petition?

These and many other questions can be asked. We do not wish to have the Food and Drug Administration issue regulations without proper and considered judgment; but on the other hand, it is impossible to start a research program based on proving the safety of these products without a knowledge of what the requirements are. True, we have individual opinion as to the definition of the pharmacological and toxicological tests which must be performed, but there is no assurance that these will not be changed when the regulations are finalized. The fact that it is impossible to define the requirements is making it almost impossible to get research in this direction started.

There are many products which have real application in the field but whose profit potential is limited, and hence, cannot be considered for development because the risk is too great for the expected return.

In conclusion, it appears to me that things are now so hopelessly confused that the time is right for a complete overhaul of legislation dealing with products which may be considered foods and drugs. I know I am not the first to suggest this. In fact, the Hoover Commission recommended that such an overhaul be accomplished. I would like to suggest that consideration be given immediately to the direction which such legislation should take in order that some kind of sense can be brought out of this state of confusion.

It is my feeling that the phrase "for man or other animals" is the basis for many of the problems which confront us today. I feel the word "other" must have sneaked into the law and should be removed. I also feel we should go further than this. One who is familiar with the regulations as they are presently written sees attempt after attempt made to clearly define the differences in specifica-

tions and requirements for products which are intended for man and for animals. I believe every one would feel better if a law would be passed which would differentiate food and drugs intended for use in man and those which were intended for use in animals. A single law and regulations should be passed governing the foods and drugs intended for man. Separate categories, such as biologicals and certified antibiotics, should be eliminated.

On the other hand, veterinary drugs and animal feed additives should be covered by separate statutes and regulations designed for them. The administration of such statutes and regulations could well be done by the extension services and the county agents of the United States. These people could do much to help educate the farmer, the grain dealer and the feed mills in the proper handling and marketing of products and their safe and reliable use. These agencies are closely allied with state feed control, pesticide control and fertilizer control people; and by this close contact, much would be achieved in obtaining real safety in the handling and use of these products.

FDA REPORTS RECENT SEIZURE

The entire stock of a new firm's vitamin-mineral and protein food supplements valued at $30,000 has been seized on charges by the Food and Drug Administration that the products were being falsely promoted to insure longevity, virility and freedom from disease. According to its promotion literature, tablets supplied by World-Wide Nutri-Health, Inc., of Pittsburgh, provide nutrients which will make the American diet equivalent to that of the long-lived people of the Hunza area in the Himalaya Mountains. FDA charged that the products were being falsely represented to promote eternal youth, virility, radiant health, sound eyesight, attractiveness until a ripe old age, and to treat and prevent such diseases as cancer, heart attacks, mumps, measles and chicken pox.

FDA also charged that representations that the American people are undernourished and that it is impossible to obtain adequate nutrition from ordinary foods, are likewise false and misleading because they are contrary to fact.

The products were seized in possession of the company. FDA said the firm was just getting under way with a sales campaign based on house-to-house promotion. The sales plan was a chain-letter type operation in which individual salesmen receive commissions on the sales of other agents they recruit.

Seized with the food supplements were various pieces of literature and other labeling materials containing the statements which FDA charged to be false and misleading. FDA said the sales plan included furnishing a free sample to prospective customers and a book on the long-lived Hunza people.

Congress and the Drug Industry

By RAYMOND D. McMURRAY

The Author Is Secretary and General Counsel, Hoffmann-La Roche, Inc. In His Address Mr. McMurray Discusses the Congressional Hearings and the Kefauver-Celler Bills and Their Effect upon the Industry.

ON APRIL 12, 1961, Senator Estes Kefauver (D. Tennessee) and Congressman Emanuel Celler (D. New York) handed up a sweeping indictment of the drug industry in the United States. On that day they introduced, with attendant press releases, identical bills S. 1552 and H. R. 6245, respectively. Significantly, these bills are titled "Drug Industry Antitrust Act."

The Kefauver-Celler bills are an outgrowth and culmination of hearings which began on December 7, 1959. Prior to that date one would have found it difficult to talk for any length of time on the subject "Congress and the Drug Industry." There was and had been until then a fine rapport built of mutual respect between the necessarily regulated industry and the fair-acting regulating body. Today, the mutuality and accord is sorely strained.

After only two years, those of us who have lived through it could probably speak volumes about the experience. Indeed, volumes *have* been spoken. Some 13 substantial volumes of testimony were taken during hearings held before the Subcommittee on Antitrust and Monopoly of which Senator Kefauver is chairman. Total pages of the printed record (available from the Superintendent of Documents) run in excess of 16,500 pages.

For those who wish to take the time, the conduct of these hearings is spread upon the record for all to see. The attack was swift, the follow-up sure, and throughout, the hearings moved relentlessly toward a preconceived conclusion.

In introducing his bill in the Senate, Mr. Kefauver made the following emotion-charged allegations in the course of his remarks:

> . . . There have been many complaints about the high cost of drugs and particiularly those which must be purchased by the consumer on prescription

of a duly qualified physician. The sick who need these drugs cannot choose between brands as in the case of most other consumer products. Consumers who pay are captives of the drug industry. They are unable to protect themselves by shopping around for the identical product at lower prices.

. . . The need for action stems basically from the fact that, by any test and under any standard, prices and profits in the ethical drug industry are excessive and unreasonable. (*Congressional Record*—Senate, April 12, 1961, page 5297.)

Incidentally, the Senator again made this statement at hearings on October 16 of this year at the beginning of the so-called "Patent Round" of hearings on S. 1552. (Hearing record page 1140.) Senator Everett M. Dirksen (R. Illinois) reminded Mr. Kefauver that his conclusions were not established, and that his statement was made to appear as a committee conclusion when, in fact, there could be no conclusion until the hearings are over, all of the testimony presented and a proper analysis made. (Hearing record page 1148.) In addition, Senator Roman L. Hruska (R. Nebraska) stated that he admired Mr. Kefauver for his persistency in restating, in the same language, these unproven conclusions. (Hearing record pages 1148-1150.)

And now returning to Mr. Kefauver's statement introducing S. 1552, he states the necessity for his bill as follows:

The time has arrived for action by the Congress to reduce the excessive and unwarranted charges upon those who are least able to afford them—the Nation's sick and afflicted. (*Congressional Record*—Senate, April 12, 1961, page 5297.)

It would be too easy for those of us who are closely associated with the drug industry to point out the numerous inequities which faced us. We were confronted with distorted and sensationalized profit margins charged against our industry and put into the record at the precisely correct moment to catch morning and evening newspaper edition headlines. We watched leaders of our industry being subjected to lines of questioning which put them constantly on the defensive. We naively approached the hearings, fully expecting a fact-finding procedure conducted in a judicious manner by statesmen, but instead, we were met with a well conceived, cleverly executed, adversary proceeding without the benefit of any of the rules of evidence prevalent, and so highly cherished, in our court systems. A rehearsal of these facts would merely tend to reiterate the obvious and would gain us nothing at this time.

What I will say is that it is my belief that we have learned a lot through the course of the hearings; and although it has taken us

these two years to recover from the shock of our first exposure, we shall attempt to put into the record in opposition to S. 1552 a positive defense of the drug industry in the United States, the same drug industry which has provided for our people the finest and most advanced health care in the world today.

Within a few days, on December 6, hearings resume before the Kefauver Subcommittee which ought to clear the record for the industry. Since that task is to be done so soon, and by experts, I shall confine my remarks to an analysis of several bills now pending before Congress which affect us and make some observations about our future with Congress and other government bodies. There may be a lesson therein for much of this audience.

First the major piece of legislation: the Kefauver-Celler bills. Briefly, this is a three-pronged attack, amending the Sherman Act, the Food, Drug, and Cosmetic Act and the patent laws. Amendments to the Sherman Act would make it unlawful (1) to withdraw pending patent applications and concede priority of invention to another applicant where a cross-licensing agreement was involved, and (2) to to discriminate in any way in the granting of patent licenses.

The bill seeks to amend the patent laws (35 U. S. C. Part II):

(1) By prohibiting the granting of patents for so-called molecular modification (which term, incidentally, is undefined) or combination of drugs unless the Commissioner of Patents finds that there is sufficient invention over the prior art so that the invention under study would not be obvious to one ordinarily skilled in the art (this is really a restatement of the present law); and in addition, that the Secretary of Health, Education and Welfare finds the resulting therapeutic effect significantly greater than products already on the market. (This provision has already been opposed by the Commissioner of Patents in his testimony before the Kefauver Subcommittee on October 16.) A procedure is set up for the determination of therapeutic effectiveness by the Secretary of Health, Education and Welfare including research which the Secretary shall cause to be conducted by the applicant or anyone of the Secretary's choosing (thereby duplicating the applicant's work), and, in addition, stating that the Secretary of Health, Education and Welfare shall have the final determination which shall be conclusive upon the action of the Commissioner of Patents in the issuance of a patent.

(2) By providing that where a patent is issued for any drug which requires a New Drug Application under Section 505 of the Food,

Drug, and Cosmetic Act, it shall be issued as of the effective date of the New Drug Application. If no New Drug Application is required, patents for such drugs shall be issued as of the date the patent application was filed. Thus, you can see this is an effective shortening for this industry only, of the normal periods of patent protection.

(3) To further amend 35 U. S. C. to limit patents on drugs to a term of three years from the effective date of such patent plus an additional period up to 14 years during which the patentee can retain his rights only if he grants to each "qualified applicant" an unrestricted license to make, use and sell the drug for a maximum royalty of 8 per cent. Should the patentee fail to honor a request for license, the patent can be cancelled if the refusal is found to be unreasonable.

It is interesting to note that "unrestricted license" is defined as one which:

(a) Must include a grant of all technical data needed for production. In other words, there will now be a statutory requirement that know-how be given along with a license which is something that has never been required under any stretch of the law or imagination to this date;

(b) Cannot contain any restriction except a royalty of 8 per cent of the gross selling price; and

(c) Must not bear a royalty rate which is discriminatory between licensees even though the same compound is sold for different uses or in different forms.

Amendments to the Food, Drug, and Cosmetic Act include provisions as follows:

(1) To require prescription drugs to be manufactured only by duly licensed manufacturers;

(2) To add to label requirements the following: (a) a manufacturer's license number; (b) quantities of ingredients; (c) an official name (generic or nonproprietary name) of equal prominence with the trademark; and (d) the date beyond which there would be reasonable doubt as to the potency of the product. Otherwise the drug will be misbranded under the Act;

(3) To provide for a label statement of the "official name" and quantity of each active ingredient after removing the present requirement that the "common or usual name, if such there be" appear on the label;

(4) To require that all antibiotics not certified under Section 507 of the Act be subject to misbranding under Section 502;

(5) To require under Section 502 that any drug information to licensed physicians must include a copy of all package insert, printed material pertaining to such drugs; and if it is a new drug, then the official brochure must be provided. In addition, all advertisements of any kind must include: (a) the official name printed in type of at least equal prominence as the trademark; (b) warning statements; and (c) full disclosure of efficacy;

(6) To amend the new drug section to require a finding of efficacy before a New Drug Application can become effective;

(7) To repeal the automatic effectiveness of a New Drug Application after a 60-day period from the date of filing without action by the Secretary;

(8) To extend present certification regulations to all antibiotics. At present there are only five antibiotics requiring certification under Section 507;

(9) To license drug manufacturers if they have proper qualifications, which qualifications would be met under standards set by the Secretary to insure strength, quality, purity, safety and efficacy of drugs produced in said manufacturing establishments;

(10) To enlarge the scope of factory inspection to include commercial testing laboratories, plant sanitation, raw materials, analytical reports, manufacturing worksheets, batch records, weighing and measuring controls, packaging techniques, sterility controls, potency controls, coding systems, qualifications of technical staff personnel and complaint files;

(11) To provide for a system for designation of official names for drugs to be determined by the Secretary on the basis of usefulness and simplicity;

(12) To provide for the Secretary to publish and disseminate an annual list of drugs having potentially harmful effects, to physicians together with copies of all required package inserts.

In implying that our industry requires such stringent added regulation, this legislation forcefully alleges that we have not met our duty to the medical and pharmacal professions and to the public to which they minister. We cannot accept the guilt which this implies, and I believe that we will prove within the very near future that we have adequately met the public trust. This legislation not only indicts

our industry, and imposes impossible burdens on the Secretary of Health, Education and Welfare and the FDA, but it also does violence to one of our most cherished and long-standing institutions—our patent system, which finds its origin in the Constitution (Article I, Section 8):

The Congress shall have power . . .

8. To promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive rights to their respective writings and discoveries.

Recently, we commemorated the 125th anniversary of the enactment of the Patent Act of 1836 which created the present examination system for the grant of patents. Unexcelled in the world—it has brought prosperity to our nation. By Proclamation dated September 22, 1961, President Kennedy recognized the value of our system of patent protection in the following words (among others):

. . . WHEREAS the grant of a patent is a traditional incentive for the promotion of the useful arts and thereby contributes notably to the well-being of people everywhere; and

WHEREAS encouragement of invention is essential to the continued economic and technological development of this Nation; . . .

He then designated the week of October 15, 1961, as American Patent System Week.

[T]o commemorate the American patent system which, by affording protection and encouragement to inventors as envisaged and authorized by the Constitution, contributes so greatly to the encouragement of inventive genius. (*Federal Register*, September 27, 1961, page 9065.)

It is this incentive, established in our founding document and recognized by the President of the United States, which Senator Kefauver is determined to take from our industry based on a conclusion that the public welfare will be properly served by stripping away adequate patent protection. Senator Kefauver seems not to believe, as Abraham Lincoln did, that patents add the fuel of interest to the fire of genius.

If he should be successful in convincing the Congress of his position, it will serve only as encouragement for the same treatment to be accorded other industries as each in turn becomes the subject of investigation and thus clothed with a public purpose.

* * *

Lest you think that the Kefauver bill, as important as it is, is the end of our problems with Congress, I will cite several other bills.

Both of the bills introduced by Mr. John D. Dingell (D. Michigan), H. R. 3747 on February 2 and H. R. 6471 on April 19 of this year, are directed toward the drug industry and seek to amend the Federal Trade Commission Act.

H. R. 3747 will amend Section 15(a)(1) of the Federal Trade Commission Act by adding that prescription drug advertising is misleading in a material respect (hence, a violation of the Act) if it does not include the generic name of the drug advertised.

It is interesting to note that the term "generic name" is not defined in the bill and that this term is in basic conflict with the term "official name" used in the Kefauver and Celler bills. Furthermore, this provision removes from the F. T. C. Act the time-honored prohibition against advertising jurisdiction of that regulatory body where such ads are directed solely to members of the medical profession which contain no false representation of a material fact, and, in each instance, are accompanied by or include a truthful disclosure of the formula showing quantitatively each ingredient of the drug. (See F. T. C. Act, Section 15(a)(1))

Mr. Dingell's other bill, H. R. 6471, also seeks to amend Section 15 of the Federal Trade Commission Act to declare that prescription drug advertising is misleading in a material respect (hence, a violation of the Act) if it fails to contain a conspicuous and truthful disclosure of the quantitative formula setting forth all active ingredients including their common names, all side effects and contraindications.

This duplicates the requirements of the present FDA labeling laws and regulations which demand full disclosure for the purpose of informing the prescribing physician of all of the activities of the drug—good or bad. In addition, note that Mr. Dingell in H. R. 6471 uses the term "common name" which adds a third and confusing designation for the so-called generic name, confusing because the Food, Drug, and Cosmetic Act states in Section 502(e)(1) that labels must bear the "common or usual name" of the drug "if such there be."

There are other bills pending, namely that introduced by Mrs. Leonor K. Sullivan (D. Missouri) on January 3, 1961, H. R. 1235, which is a perennial bill amending the Food, Drug, and Cosmetic Act. H. R. 646 is a bill introduced by Mr. Hale Boggs (D. Louisiana), dated January 3, 1961, to regulate the manufacture, processing, distribution and possession of habit-forming barbiturate and amphetamine drugs; a bill by Mr. Winfield K. Denton (D. Indiana) designated

H. R. 3967, introduced February 7, 1961, which is comparable to Mr. Boggs' H. R. 646; and S. 1939 introduced by Senators Thomas J. Dodd (D. Connecticut) and Alexander Wiley (R. Wisconsin) which regulate barbiturates and amphetamines as does H. R. 646.

* * *

Any message which I might give to you today may be stated very simply: It can happen to you! Drugs are necessities from time to time for all of us. Their use is wrapped up in the emotional stress of illness. Hence, objective thinking is extremely difficult. Foods are also necessities, but never as occasionally as drugs. We have daily need for nutritional products; and although the emotions attendant upon illness do not bear on foods, one could think of greater emotions being aroused if charges were made that unconscionable profits were being taken from an unsuspecting public by unscrupulous profiteers dealing with our daily bread.

It might be difficult for you, as it was for us two years ago, to see how anyone could possibly paint a picture that was anything but laudatory describing the industry which you know is fulfilling its proper purpose and recovering only a just reward for so doing. Do not, however, underestimate the ability of Congressional hearings to create situations you think are distortions but which must inevitably serve the politico-legislative purpose for which they are created.

At any time a Congressional committee can find glamorous headlines in the food, packaging and allied industries. You have seen what our recent brushes with Congress have done for our public image, and I hope you will realize that you are not immune. Pay particular attention to the techniques of Congressional investigation. Do not suppose that they are anything but an adversary proceeding and prepare your defense accordingly. Above all, never minimize the adverse publicity effect when Congress calls you before one of its spotlighted committees.

There is a lesson in some of the mistakes we have made. When the history is finally written I have no doubt that we will be better off for the experience. We have matured under fire. Some years hence Congress and the drug industry will return to their former mutual regard. Take a good long look at what has happened to us and prepare now for a day which seems inevitable in your lives. I cite only the recent investigations regarding packaging within the food industry to show that Congress is very close to your door. **[The End]**

Proposed Inspection of Independent Laboratories

By BERNARD L. OSER, Ph.D.

The Author Is President of Food and Drug Research Laboratories, Inc. In His Address, D. Oser Speaks of the Proposed Extension of Authority of the FDA.

THE OBJECTIVES of the current Congressional investigations of the drug industry are reflected in the Kefauver bill S. 1552 (and its identical counterpart introduced by Rep. Emanuel Celler, H. R. 6245, 87th Congress, 1st session), one section of which would amend the Federal Food, Drug, and Cosmetic Act in several major respects. Among these (Sec. 4(13)) is an amendment to Section 508 of the Act whereby

> (c) Any officer, agent, or employee of the Department authorized by the Secretary for that purpose may during all reasonable hours enter and inspect any establishment operated or intended to be operated within any State by any licensee or any applicant for a license under this section for the manufacture, preparation, or propagation of any drug described in subsection (a). Such plant inspection shall include, but is not limited to, the right to inspect commercial testing laboratories, plant sanitation, raw materials, and analytical reports on such materials, formula cards, actual manufacturing working sheets, batch records, weighing and measuring controls, packaging techniques, sterility controls, potency controls, coding systems, facilities for maintaining separate identity for each drug, cleaning of equipment between batches, quarantine of drugs until after clearance with the control laboratory, qualifications of the technical staff, and the complaint file of the licensee or applicant.

The granting, revocation or suspension of a license to produce prescription drugs would be contingent upon the determination by the Secretary that the results of such inspections (among other requirements) establish that drugs are "manufactured, prepared, or propagated under the conditions necessary to insure the continued chemical structure, strength, quality, purity, safety and efficacy" of such drugs. Fines or imprisonment may be imposed on anyone convicted of obstructing or interfering, or attempting to obstruct or interfere with any officer, agent, or employee of the department in the performance of any duty pursuant to this section.

As described by Secretary Ribicoff in his testimony before the Kefauver Committee, the proposed new inspection authority is aimed at giving the Food and Drug Administration more direct and more extended control over the drug industry. As thus amended, it would, in short, permit inspection of a drug company's building, plant and equipment, its manufacturing operations, formulas and complaint files, its analytical control laboratories and facilities, and it would even authorize inspectors to review the training and experience of its scientific and technical personnel. In his testimony, the Secretary stated that in the 32 months ending August, 1961, 122 firms had refused to permit one or more phases of inspection "needed to make a complete determination of the legality of some phase of the drug business." This statement does not suggest whether any of these firms were independent laboratories or whether any phase of these inspections concerned the manufacture or control of drugs as distinguished, for example, from purchase or sales records, complaint files, or labeling. In fact no analysis of the nature or basis of these refusals has been presented which would justify an estimate of the extent to which commercial testing laboratories were involved, if at all. Analysis of these refusals might furnish the key to determining whether, in fact, there is a real need for additional legislation to extend the authority of FDA in this particular area.

In a recent notorious case, the operator of a commercial laboratory pleaded guilty to submitting false reports to pharmaceutical manufacturers, on the basis of which their drugs were found to be adulterated and misbranded. In addition to a fine, the sentence included 3 years' probation. Subsequently conviction for repetition of the offense resulted in an additional fine and six months imprisonment. This extremely rare case of gross misconduct has directed special attention to independent laboratories which perform analytical control services for the drug industry.

No competent and responsible laboratory will object to showing its facilities and discussing its qualifications for providing the services it purports to offer. In fact the opportunity to do so is usually welcomed regardless of whether the visitors are clients, prospective clients, domestic or foreign government agents, teachers, students, or the general public. Reputable laboratories, such as those represented by the membership of the American Council of Independent Laboratories, are not only proud to display their wares but are ready and willing to participate in any effort to curtail the activities of the small

fringe of incompetent or dishonest operators. However, since any law designed to remove the one rotten apple at the bottom of the barrel inevitably affects all, it has been necessary to examine carefully the scope of these inspection provisions particularly as it concerns the relation between a laboratory and its clientele. Nowhere does the Kefauver-Cellar bill define a "commercial testing laboratory." It is pertinent to cite the definition currently adopted by the American Council of Independent Laboratories since this is the only national organization whose membership is composed exclusively of such laboratories.

> An independent laboratory is a proprietorship, partnership, or corporation which is not affiliated in any manner with either a governmental agency or a tax-favored academic or research institution; or with an outside proprietorship, partnership, corporation or trade association in any manner which may jeopardize its capacity to conduct investigations, render reports, or give professional counsel objectively and without bias.

The by-laws of this association require each member to honor a code which commits them not only to maintain their services upon a "high plane of integrity, effectiveness and reliability" but to protect the rights and interests of clients.

Independent laboratories are not only desirous of supporting any legislation designed to promote public health and welfare but are especially interested in any effort to stamp out unfair or dishonest activities on the part of any practitioners of its professions. However, it is believed that aside from the manufacturers' own laboratories and commercial testing laboratories, many other institutions and individuals play a role in evaluating the efficacy, safety, quality and potency of drugs. Among them are medical schools, universities, research institutes, hospitals, clinics and even private practitioners of medicine, dentistry and allied professions. To single out commercial laboratories for the purpose of this legislation is discriminatory. Furthermore, certain aspects of federal inspection warrant careful consideration especially in light of the fact that recent experience has shown an unanticipated degree of expansion of the scope of basic food and drug legislation when interpreted in administration regulations. Of particular significance is the possible effect of such legislation on the relation between a laboratory and its clients.

It is understood that the Department of Health, Education and Welfare is preparing its own bill for presentation to Congress, which will extend similar authority to its agents. With a view toward obtaining guidance in the formulation of its policy vis-a-vis the proposed

expansion of its inspection authority the ACIL decided to direct certain questions to the Secretary of Health, Educational and Welfare.

Accordingly, under date of March 15, 1961, a letter was addressed to Honorable Abraham Ribicoff, Secretary of the Department of Health, Education and Welfare, in which certain questions were raised. The Secretary's reply, enclosing comments prepared at his request by Food and Drug Commissioner George P. Larrick, was somewhat delayed because the proposed legislation (that is, the department's bill) is still under consideration.

For convenience the ACIL statements and queries, as presented here, are followed seriatim by the replies of the Commissioner which are quoted in full with his kind permission:

(1) It is understood that a recent conviction in an action brought by FDA in Philadelphia was based on dishonest reporting by a laboratory inadequately equipped to render the services claimed, resulting in the misbranding of a number of pharmaceutical products of its clients.

Query: In what respect are present laws inadequate to deal effectively with such a situation?

Answer: "When the present factory inspection provisions of the Food, Drug, and Cosmetic Act were being considered by Congress, a legislative history was developed on the floor of the House indicating that some members of Congress did not intend the inspection provision to give the Food and Drug Administration authority to look at certain records including formula files. Some manufacturers have interpreted this to mean that they do not need to allow our inspectors to examine various control records, and because of the legislative history, we have not considered it wise to bring legal actions because of their refusal. This creates a loophole in the law that interferes with good enforcement and should be remedied by amendment.

"Moreover, the need for clear authority to inspect control records is as great where an independent laboratory conducts control analysis for the manufacturer as where the records are in possession of the firm that compounds the drug. As pointed out in testimony last year before the Kefauver Subcommittee (Subcommittee on Antitrust and Monopoly of the Senate Judiciary Committee), we interpret the present law (Sec. 702 of the Food, Drug, and Cosmetic Act) as giving us authority to inspect commercial consulting laboratories to the same extent as drug manufacturers' plants where the laboratory is used as part of the manufacturer's controls (e. g., by performance of

assays), but we believe that it would be desirable to make this clear in the law beyond question at the same time that the inspection provisions are otherwise clarified and strengthened. See, in this connection, Sec. 2 of H. R. 12949 and S. 3815, 86th Congress."

(2) Members of ACIL not only permit but welcome inspection of their facilities by representatives of government as well as industry.

Query: Has the FDA or any government agency ever experienced refusal on the part of an ACIL member, or of any independent laboratory, to allow a qualified representative to visit or inspect its premises?

Answer: "The extent to which outside control laboratories participate in the drug development and control procedures of this country only became apparent within the recent past. There have been few occasions on which we have attempted to inspect independent laboratories. We do not recall any instance of refusal to permit inspection of such a laboratory.

"Thus, the desirability of mentioning independent laboratories in connection with any new legislation is not, so far, occasioned by refusals of such laboratories to permit inspection. Rather, there is a need to have the law perfectly clear regarding our authority to inspect such concerns."

(3) "Inspection" is a broad term which in its most exaggerated sense can include examination, not only of physical facilities and equipment but of laboratory note books and reports, correspondence files, financial records, etc.

Query: How broadly is it intended to define the scope of inspection?

Answer: "Sufficiently broad to determine whether the control laboratory was rendering a service to the manufacturer that would forewarn him of the situations in which he had manufactured products not suitable for distribution in interstate commerce. There is no need for, and we do not desire, mandatory authority to inspect things that have no bearing on that question, e. g., financial records."

(4) A distinction must be drawn between inspection as related to a specific legal action, taken or proposed to be taken, by a government agency and inspection for the general purpose of validating or approving the competency of a laboratory in a given area.

Query: Is it the intention that inspection be limited to the former situation or do the proposers of this legislative plan intend to establish the equivalent of a Board of Certification?

Answer: "There is no 'legislative plan' under study beyond inclusion of clarifying reference to these consulting laboratories within the regular framework of the inspection provisions of the Act, with those provisions themselves generally clarified and strengthened as above indicated. This would not establish the equivalent of a board of certification. It would merely permit the inspection of those phases of an independent laboratory's operations that have a bearing on the legality of foods, drugs, or cosmetics, whether or not a specific legal action is in prospect."

(5) The relation between the professional scientist, operating an independent laboratory, and his client is generally regarded as a confidential one, not unlike the relation of the legal and medical professions to their clientele.

Query: What controls over inspection are contemplated which would preserve this indispensable right of clients to consult with scientific advisers on a confidential basis and which would permit testing and research services of a strictly private nature?

Answer: "We do not desire to authorize Food and Drug Inspectors to delve into matters of a strictly private nature. However, we qualify this by pointing out that where manufacturers are producing food, drugs, or cosmetics for consumption by the public, the manufacturing and testing activities designed to show whether the output of the plant is a hazard to the public health or is otherwise in violation of the law should be open for inspection by the Government regulatory agency.

"Employees of the Food and Drug Administration are prohibited under Section 301(j) of the Food, Drug, and Cosmetic Act from making unauthorized use of any information acquired under authority of the factory inspection provisions concerning any method or process which as a trade secret is entitled to protection. See also 18 U. S. C. 1905." [1]

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[1] 79th Congress Public Law 404, Section 3.

Except to the extent that there is involved:

(1) Any function of the United States requiring secrecy in the public interest; or

(2) Any matter relating solely to the internal management of an agency;

(a) *Rules.* Every agency shall separately state and currently publish in the Federal Register;

(3) Substantive rules adopted as authorized by law and statements of general policy or interpretations formulated and adopted by the agency for the guidance of the public, but not rules addressed to and served upon named persons in accordance with law. No person shall in any manner be required to resort to organization or procedure not so published.

(6) It is presumed that the proposed legislation has its genesis in the desire to insure adequate protection of public health and welfare particularly in the valuation of new foods, drugs, cosmetics and devices. Research and testing of these products is done, not only in independent laboratories (such as are represented by ACIL membership) but also in colleges, hospitals, research institutes, and by physicians, dentists, etc. in private practice.

Query: Is it the intention to limit the scope of proposed inspection to independent laboratories or to extend it to include all laboratories engaged in evaluations for safety or efficacy?

Answer: "Clear authority is needed for inspection of any laboratory which offers services to aid a manufacturer in the marketing of his food, drug or cosmetic. The Food and Drug Administration needs adequate authority to determine whether the article is in compliance with law, and any information bearing on this, including the reliability and significance of data developed by an independent laboratory, should be open to inspection."

(7) It is a function of government to provide for public safety not only as related to health but to physical security as well. A great deal of the work of independent laboratories concerns the safety of structures, transportation, textiles, etc.

Query: Are current laws not adequate to insure reliable laboratory services in these areas and, if not, how far is the proposed legislation intended to extend?

Answer: "See answer to question 1. Any proposed legislation would be an amendment of the Food, Drug, and Cosmetic Act and thus would extend only within the jurisdiction of that Act. It has nothing to do with tests concerning the safety of structures, transportation, or textiles."

(8) The ACIL is not opposed in principle to any steps that might be taken, officially or otherwise, to help maintain a high level of competency and integrity in the laboratory profession. If Federal inspection should be deemed by Congress to be necessary in the public interest, ACIL would support such legislation provided proper limits and controls are written into the law to avoid discrimination against the independent laboratory and to insure maintenance of a professional client relationship.

Query: How can ACIL cooperate most effectively in the drafting of new legislation with these ends in view?

Answer: "We suggest that the ACIL study the factory legislation inspection provisions of the bills above referred to in the light of the comments we have made above, since those provisions constitute a point of reference for our own study. If it then has further questions or suggestions, we would be glad to discuss them in detail. If the Council has alternate legislation in mind, we would be glad to review a draft containing its proposals and to offer comment."

Congressional hearings on the Kefauver-Celler bill are still in progress but thus far they are concerned principally with antitrust and patent aspects. Several ACIL members have addressed comments on the laboratory inspection problem to their representatives in Congress. There is, of course, no quarrel with the general purpose of legislation to insure that drugs are properly controlled at all levels of manufacture and testing. If it should be established that inspection of independent laboratories would contribute significantly to the exercise of this regulatory function we of the American Council of Independent Laboratories would not oppose such legislation. Inspections conducted within reasonable limits in relation to specific matters and not as fishing expeditions, it is generally agreed, might tend to favor reputable laboratories and discourage marginal operators.

The inspection provision in the Kefauver-Celler bill, however, which sets up commercial testing laboratories as the only target for inspection outside a drug manufacturer's own establishment, discriminates unduly against them by implying that the public health purposes of the legislation require that only such laboratories merit the scrutiny of federal inspectors. As a matter of fact, the quality, safety and efficacy of new drugs depend to a far greater extent on work performed in hospitals, clinical laboratories and in educational and governmental institutions, than in independent laboratories. The advertising in any medical journal will reveal the extent to which the claims for new drugs are based upon published and unpublished reports from clinics and laboratories that would be exempt from inspection under the terms of the Kefauver-Celler bill.

It is regarded as an inalienable right of individuals and companies to consult privately and confidentially with their scientific advisors, as with their legal counsel. Notwithstanding the Commissioner's objectives of inspecting laboratory operations "whether or not a specific legal action is in prospect" it would appear to be essential either in the statute or by regulations, to preserve privacy in the relation between a consulting laboratory and its client.

As indicated in his reply, the Commissioner has invited suggestions and has agreed to review and discuss drafts of any proposals we are inclined to make. With this in view, it is suggested that in place of the Kefauver-Celler proposal a new clause be added to Section 704, the factory inspection clause of the Federal Food, Drug, and Cosmetic Act, to extend the present authority of duly authorized officers or employees of the Food and Drug Administration to permit inspection under prescribed conditions. This matter is presently under consideration and in due course a specific proposal will be made.

[The End]

CARE AND MEDICO MERGE

Two international aid agencies—CARE, which sends food and self-help supplies abroad, and MEDICO, founded to serve as "physicians to the world"—will join forces next month.

Murray D. Lincoln, board chairman of CARE, Inc. (Cooperative for American Relief Everywhere), and Dr. I. S. Ravdin, board chairman of MEDICO, Inc. (Medical International Cooperation Organization), today announced the merger, voted by both boards of directors. Details will be completed by mid-February.

MEDICO, co-founded by Peter D. Comanduras and the late Dr. Tom Dooley, will operate as a service of CARE. It will continue to send teams of American doctors, nurses and technicians overseas to augment medical and clinical health services, training and education, while CARE assumes administration and provides material support. Dr. Comanduras, secretary-general of MEDICO will continue in charge of the MEDICO program, as assistant executive director of CARE.

Thus, CARE will gain a professional arm for the medical supplies and equipment that form part of its self-help assistance. In turn, MEDICO will be able to concentrate on, and expand, its professional role in improving health conditions.

The American public will share the benefit, the chairmen pointed out, of two additional results: reduction in administrative costs, by eliminating duplicate facilities, and a decrease in the multiplicity of fund appeals.

MEDICO, founded in 1958, currently has 20 medical teams and programs in 12 countries. Ten of the leading American medical and surgical associations, including the American College of Surgeons and the American College of Physicians, have affiliated with MEDICO during the past years. Specialty sections include the International Eye Bank and the Orthopedic Overseas Division. In the past fiscal year, it dispensed nearly $2,000,000, including $1,000,000 in donated drugs and equipment, to combat disease and suffering in critical health areas.

CARE, founded in 1945, now operates in 32 countries. Total value of aid distributed in the past fiscal year reached over $53,000,000 including agricultural foods donated by the U. S. Government. Public donations totaled $9,955,430 of which one-third was used to provide health, educational, farm and vocational "tools," to help the needy help themselves to a better future.

Current Food Additive Problems

By KENNETH E. MULFORD

Mr. Mulford Is the Executive Vice President of Atlas Chemical Industries, Inc. A Section of His Address Is Devoted to the Second Citizens Advisory Committee.

THE PAST FEW YEARS might be called the "Age of Trying to Catch Up."

Scientifically and technologically, the food and chemical industries achieved significant advances in the past few decades. These advances helped to improve our food supply, to increase the yield of our farms and to overcome the age-old problem of "farmed-out" land.

But it has taken time for legislation to catch up. For years we were confronted with the poisonous per se doctrine of the food and coal tar color sections of the law. With the exception of the cancer clauses, that doctrine has been changed by the Pesticide and the Food and Color Additive Amendments.

Now that we have new legislation, we are confronted with the inevitable problems of compliance with and of effective and efficient administration of the laws, as well as the recruitment of competent personnel to enforce them. The magnitude of this task is far larger than originally anticipated.

A decade ago, the Special House (Delaney) Committee talked about 850 food chemicals. Now FDA estimates, I understand, that there are more than 1,000 chemicals used in foods, and that the figure is nearer 4,000 if incidental additives are included. The burden of supplying data to FDA regarding these products—the data which forms the basis for FDA judgments and subsequent regulations—falls primarily upon industry. All of this represents a tremendous job both for industry and government, for we are talking about some 6,500 producers of chemicals for use in food who are supplying an estimated 73,000 manufacturing and processing plants.

Finally, all of us at this conference still face the serious lag in public understanding of the contributions of modern science to our

food supply, both in terms of farm production and food processing. There still are publications taking the stand that the statute books are devoid of laws adequately protecting the public against "food poisoning." However, there are some hopeful editorial signs which I shall touch upon later.

Years of intensive activity should always be interspersed with moments of reflection on how well we are doing; we must try to anticipate and plan soundly for problems that may lie ahead. One of the principal values of such conferences as these, it seems to me, is that they afford an excellent opportunity for stocktaking.

To those of you who stayed up many nights trying to determine which substances were covered under the 1958 law, which might qualify as generally recognized as safe (GRAS), what data would be required to support petitions and how the regulations proposed in the petitions should be worded, it will come as no news when I say that the law imposed heavy burdens on government and industry. Similar problems, of course, have been encountered with other recent amendments to the law.

I am certain there is general agreement that FDA has striven conscientiously to administer the law with a high degree of fairness. But there are, I believe, some trouble spots on the horizon, and I feel they should be discussed with candor. Government and industry have a tremendous stake in the efficient and effective administration of the 1958 food amendment, not to mention the other sections of the Food, Drug, and Cosmetic Act. It is to our mutual advantage that we resolve these problems that may arise, and it is in this spirit that I wish to raise several points today.

First, let me point out that our experience with prior approval of food, drug and cosmetic ingredients before the 1958 Food Additives Amendments was limited to new drugs, coal tar colors and pesticide residues. Of these, only pesticide residues, which are usually very minute amounts of highly specific chemicals, were controlled by published regulations. As you know, the specifications in new drug applications are confidential and the old coal tar color control was largely by batch certification. Consequently, for all practical purposes, a second, third or fourth producer of a new drug or coal tar color also had the burden of establishing the fact that his product met the requirements under the act.

Prior to the 1958 amendment, food additive producers or users were responsible for their own manufacturing standards and specifi-

cations. However, under the food additive regulations of the new law, a petitioner files with FDA all pertinent information relating to the chemical identity and composition of the additive, with specifications prescribing any reaction byproducts. If the additive is a mixture of substances or a complex reaction product, as many of them are, a list of all chemicals used in the synthesis is required.

Product specifications in FDA regulations are based on this information in the petition. Thereafter producers and users, other than the petitioner, determine whether their products are in compliance by referring to the specifications of the regulations. It is important to note in this connection that they are not bound in any way to produce their product in accordance with the synthesis or by the use of raw materials, catalysts and the like described by the petitioner, except insofar as these items are set forth in the regulation.

It seems to me that if the petitioner is required to submit all of this information to FDA, others who make similar products should be required to do likewise. At the very least, they should be required to establish that their product is identical with the product which underwent safety tests for its intended use. It is entirely possible that a product meeting the specifications of a regulation but made in another manner or from different raw materials might differ in some respects from the product which was originally subjected to safety-testing. Admittedly many such variations would be of no significance. If any such variation should prove harmful, however, confidence in the ability of the law to protect the public would be greatly undermined.

In a more general way, a specification problem also exists with respect to the GRAS and prior sanction listed substances designated "food grade" or "suitable for association with food." Many of these substances have no regulatory specifications at all. It is hoped, however, that the Food Chemical Codex project under the auspices of the Food Protection Committee of the National Research Council will be helpful in solving this more general problem.

It also seems to me that if industry petitioners provide, as they have done, most of the data which support the regulations, there should be some way in which a petitioner could be advised of the proposed regulation and a forum designated before which the petitioner could formally present his view on the regulation before it is published in the *Federal Register*.

Another fundamental question is whether FDA's present staff and organizational structure is capable of handling the tremendous burdens which have been imposed upon the agency since the Citizens Advisory Report of 1955. Since that time, as you will recall, there have been three major pieces of legislation: the food and color amendments and the Federal Hazardous Substances Labeling Act.

In addition, FDA is expected to seek legislation to strengthen its factory inspection authority and gain additional regulatory authority with respect to cosmetics, etc. Quite clearly the enactment of all or even most of these proposals would add still further burdens upon FDA.

We could argue far into the night on what constitutes an efficient and effective administration of the law, but suffice it to say that I think these three minimum conditions must be met:

(1) It must be administered to afford protection to the public.

(2) It must be administered reasonably and on a sound scientific basis.

(3) It must be administered efficiently to make the best use of research facilities and the manpower of the agency and industry.

The appointment of a new Citizens Advisory Committee offers a very much needed opportunity to review the current status of FDA's operations. In announcing the new committee, the Secretary of Health, Education, and Welfare stated that we need a new evaluation of the amount and kind of consumer protection needed, the adequacy of present resources to provide that protection, the changes required to get it, and the time it will take to reach the objectives.

In considering the amount and kind of consumer protection needed, let me express the hope that the committee will consider whether the research required to solve some of the major problems under the present law really provides any commensurate protection. For example, a group of suppliers of one class of ingredients used in the paper and paperboard industry has spent over one quarter of a million dollars in research to establish that these ingredients which, incidentally, have been used for over 30 years, do not migrate into foods from paper and paperboard food wraps, including the ordinary paper bag in which your fruits and vegetables are placed in the market.

We should remember that there are and always will be finite limits, both to the number of research people and to research facilities in this country. If we are to preserve and strengthen our

position in a turbulent world we must utilize these resources with great wisdom. I therefore suggest that the new committee seek industry views regarding the magnitude and importance of the many unexpected problems, such as the one I just mentioned, that have been and will be encountered. And while I am on the subject of research, I want to urge the committee to bear in mind that industry's resources are a very important part of the facilities engaged in the task of protecting the public.

In considering adequacy of resources, let me also express the hope that the committee will not concern itself merely with budget and staff for day-by-day operations. If the vast coverage of these laws is to be handled effectively, FDA also must have adequate time and personnel for planning its internal organization structure, with clearly delineated lines of responsibility and authority.

In view of the highly technical nature of rulings and regulations —both in a legal and scientific sense—background and training of personnel are of great significance, as is an organization which provides good communications and a highly developed within-job training program. Structurally, it is no easy task to provide adequate coordination and communications in any agency that has in addition to a scientific staff, divisions for the development and issuance of approvals and regulations and a division for enforcement. Nor it is always easy to recruit and to hold competent personnel at government salary levels. The willingness of so many able FDA staffers to remain with the agency over a long period of years is, indeed, a tribute to their spirit of public service.

In conclusion, I want to touch rather briefly on a point I mentioned near the outset: namely, the lag in public understanding of the contributions of modern science to food and agriculture. Gaining public understanding and confidence is often a slow undertaking, especially when it concerns the complex scientific issues necessarily involved in food additives, and when it is so simple to prey upon public fears of this or that disease.

Most of us in the food and chemical industries favored passage of the pesticide amendments, the 1958 food and 1960 color amendments. We had, to be sure, our misgivings about the unscientific nature of the food and color cancer clauses—misgivings which many of us feel have been confirmed—and we would have preferred a different

approach than prior approval. But we all agreed on the need for pretesting.

Moreover, many of us felt that legislation, administered by a widely respected agency of government, would serve in the long run to overcome a great deal of public apprehension over the use of chemicals on the farm and in foods. There were many factors behind this apprehension—the statements of some of the witnesses before the Delaney Committee, sensational scare articles in magazines, newspaper stores about the 1956 Rome meeting of the International Union Against Cancer, books by food faddists and writers who believe it is more blessed to receive royalties than to contribute to public understanding.

Even though attacks continue, progress has been made. This has not been the result of the efforts of any single group. FDA, for instance, has played a significant part, both in terms of speeches by responsible officials and preparation of background material. Mention must be made, too, of the reports of the National Academy of Sciences —National Research Council.

Those of us who are members of the Manufacturing Chemists' Association are encouraged by the results of the MCA public relations program on food additives. Most of you, I am sure, are familiar by this time with the excellent booklet, "Food Additives—What They Are —How They Are Used." As you also perhaps know, MCA and the Nutrition Foundation cooperated in carrying out an educational program to reach home economists, nutritionists and dieticians, home demonstration agents, public health leaders, food editors, writers and librarians. The association is following this up with a continuing program.

Any review of recent clipping will show that food additives are now being mentioned favorably by a number of food columnists and other writers. We have gained some yardage, but we cannot afford to relax.

By this time next year we should know the recommendations of the new Citizens Advisory Committee. As Commissioner Larrick said in this year's appearance before the House Appropriations Committee, the 1955 citizens advisory report made "very substantial contributions." If FDA is to successfully meet its vastly increased responsibilities, I am personally convinced it needs the assistance of such an outside group once again and I hope that we in industry will have the opportunity to offer constructive suggestions. **[The End]**

The Effect of the Food Law on Packaging Materials

By ADOLF MILLER

The Author Is Vice President, Research and Development, Milprint, Incorporated. In His Address, Mr. Miller Discusses the Effect of Public Law 85-929 upon the Flexible Packaging Industry.

INDIVIDUALS FROM MY INDUSTRY seldom have an opportunity to appear before public or semipublic groups, since what the industry does is not something tending to give it any great significance in the mind of the public.

The industry I refer to is that supplying flexible packaging materials, largely to food processors. Essentially, it is a converting industry which takes raw materials from a group of suppliers, does something to these raw materials and sells them to another industry which utilizes its products to form finished items sold to the consumer. Thus, it is a step away from the consumer and the consumer knows little about it and probably cares less. Because it is a converting industry its profit margins per unit produced are relatively small and it must depend on large volume in order to be profitable.

When Congress passed Public Law 85-929 on September 6, 1958, this industry found itself directly concerned with some of the legal and safety aspects of the food and drug industries, its major customers. The law had defined a food additive as any substance directly or indirectly becoming a part of the food product. The package, thus, became a part of the finished product and had to be treated in a manner similar to the product itself from the viewpoint of potential health hazards. The demonstration of safety rested on the food producer, that is, our customer.

There is little point in reviewing the history of the past several years concerning the actions taken by the flexible packaging industry in making the effort to conform with the new law. The food industry passed back to us the responsibility for demonstration of safety of the packaging materials and we, in turn, passed back to our suppliers (the chemical industry) the demonstration of safety of the materials we use, with the exception of those formulations where we had a proprietary interest.

In the effort to conform to the law, the chemical industry has responded well, and, with the guidance of the Food and Drug Administration in accumulating sufficient and proper data, a large number of substances have been allowed for use in packaging through the classifications of GRAS, prior sanctions or extensions, pending completion of work being done on specific materials. However, some immediate and permanent effects of the law exist:

(1) The general recognition of safety of a package as being important by the top management of our industry.

Prior to the existence of the law our approach had frequently been that package safety was a self-policing matter. If the package were not suitable for the product, failure of the package would show up in one way or another and such a package would automatically eliminate itself from the market. However, with the passage of the law we find ourselves much more closely involved in our customers' problems and this has been recognized as part of the responsibility of our industry.

(2) The problem of safety of packaging materials has been recognized as an industry problem and we have learned to cooperate in the exploration and accumulation of technical information. For example, the Glassine and Greaseproof Manufacturers Association made studies of plasticizer migration and sizing migration for the industry as a whole; the polyethylene producers supported a program of extraction studies and animal feeding tests and the American Petroleum Institute supported a similar program on waxes, all tending toward the development of food grade specifications.

(3) In individual organizations we were forced to classify and codify the materials which we used in our products. Part of this involved collection of existing toxicological data and study of specific ways in which materials were used. Many of the products we pro-

duced were made in relatively archaic ways and the study we were forced to make caused improvements in these products.

In addition, we studied the package end use much more closely and set ourselves up to do rather intensive extraction studies.

In order to do these studies advanced scientific methods were brought into an industry which had never required the use of such methods. For example, in our extraction studies we have used infrared spectroscopy and gas chromatography in order to accumulate reliable data. Since we had these instruments we also used them for investigation of a large number of the raw materials our suppliers sold to us—investigations not concerned with establishment of safe use of these materials and we have learned a great deal more about them. Our suppliers, of course, now find themselves in a position where, in many instances, we know more about what they are selling us than they know themselves.

(4) Lastly, the public, of course, has the assurance of the safety of the package in addition to the product which it packages.

By and large, although it has been somewhat painful for us to adjust to the new law, the effects to date have been good, since it has forced industries, such as the flexible packaging industry, into a greater consciousness of its responsibilities to the consuming public and has stimulated it into taking the mystery out of its own operations, in addition to giving the consumer greater assurance that the product he purchases represents no hazard.

However, there are some long range effects of the law which pose problems both technological and economical.

One of the first technological problems to arise: How does one prove that *no* migration occurs? The Food and Drug Administration has set up a series of simulated food solvents and a procedure for performing extraction tests under conditions representing the most severe usage of the packaging material. From these tests, conclusions are to be drawn as to whether extraction occurs and how much.

Using these solvents, it becomes simple enough to determine a total extract. The problem arises when one must identify what has been extracted, particularly when one is dealing with organic plastics in the form of coatings, adhesives or films. In most instances, the plastic itself does not consist of a single chemical species. It will cover a range of molecular weights, a range of structures and a group of

minor additives in the form of stabilizers, antioxidants, plasticizers, pigments, etc., whose technical effects are important to produce the desired results. In many instances these are complex structures, difficult to identify. Yet, in order to prove safety in use, the components of the extract must be identified. This will require the development of a methodology for the identification of a number of chemical entities whose identification today is not clear. The direction in which these identification procedures must go is that of advanced instrumental analysis.

We now come to the problem of how much migration is safe. Is it one part per million? Is it one part in ten million? Is it one part per 100 million? The Food and Drug Administration replies that this depends on the substance, its pharmacological properties and its toxicology. Thus, if an unknown chemical entity can be identified in an extract from some complex plastic structure by use of, let us say, an infrared absorption spectrum in a concentration of one part in ten million, the Food and Drug Administration can argue that since such a compound has not been studied in the past and that data on its toxicology are not available, even so small a quantity as one part in ten million might present a hazard, and therefore feeding tests are required.

If the substance in question is suspect as being of a carcinogenic nature, the plastic from which it has been extracted may automatically be ruled unsafe for foods under the Delaney Amendment.

The quantitative question arises in another sense. Let us suppose an organic molecule "X" has demonstrated that, under certain conditions, it may cause cancer in some test animals when fed at certain dosage levels. Under the Delaney Amendment, no "X" may be permitted in a food product.

Let us suppose that a plastic material "A" has wide usage in the food packaging field. Extraction tests indicate that no compound "X" is found, utilizing methods available today. Some years hence, analytical procedures develop, let us say, to a sensitivity of one part in several billion. Using these newer procedures, compound "X", a potential carcinogen, is found in the extract from plastic "A". Under the law, plastic "A" may no longer be used in food packaging.

Thus, judgments of safety for certain materials, under the law, may become a function of the state of the science of analytical chemistry rather than real considerations of what may or may not be safe. The

Delaney Amendment raises the whole question of "how small is nothing."

New developments in packaging are of two kinds—constructional and material. New packages can be developed by combining old materials or converting them into a new form. But an important part of packaging development has been concerned with new materials. In a sense, there has been competition between the formulation and new-form development of old materials and the introduction of new ones.

The proof of safety for a new material will become an important part of development work. Since the chemical industry will have most to say about proof of safety, it will also have most to say about what chemicals it will or will not study. Statements have been made by some chemical companies that, because of limited markets, the justification for the expenditure for proving safety of some chemicals does not exist. If a user wishes to develop food packaging applications for these substances, the burden of proving safety then rests with him. He must consider carefully whether the reward justifies the effort, since, in many cases, a new development in the packaging field cannot wait two years for the completion of chronic toxicity tests.

One effect of the law will be to increase the power of the chemical industry over the packaging materials industry. Where new chemicals are found having unique effects, or new uses of old chemicals give similar effects—thus yielding the package supplier a proprietary item —if the chemical company producing the raw materials does not wish to develop the information needed for proof of safety, the package supplier must do it himself or abandon a proprietary position.

Second, it will, at least initially, slow down the pace of new developments because of additional costs and time consumed in development.

Third, it will be used, with varying degrees of success, as a competitive weapon. Organizations equipped to gather data required to obtain approval of the Food and Drug Administration for their materials will be in a better position to promote the sale of these materials to the packaging industry than those not equipped to accumulate the needed data. The law will thus militate in favor of larger companies with greater resources and against those not having the financial strength to support a program of toxicological investigation.

Fourth, among those suppliers of packaging materials in a position to do so, there will be a tendency to develop products having application outside of food packaging, so that it will not be necessary to contend with the requirements of the law.

Last, because of increased development costs and broadened financial responsibility placed on suppliers in the form of guarantees, packaging costs will tend to rise. These added costs will be reflected in rising prices of finished products to consumers.

This law is the result of many hours of hearings and of extensive study on the part of Congress. It is part of the general pattern of legislation dealing with the welfare of our population, striving for greater security through federal intervention in almost all areas of our lives. The legislation under discussion is an effort to secure the quality of food product and food package to the purchaser of the product. Accomplishing this security will add to the costs of producing food and packages by putting an additional expense on the industries associated with food production and by increasing government costs by requiring the expansion of the agency or agencies charged with the enforcement of these regulations.

It is obvious that the people, as represented by Congress, are prepared to accept these additional costs, since the security obtained by the legislation is considered desirable.

We, who are associated with industries relatively close to the consumer, must expect that there will be additional legislation of this nature and we must develop, within our own businesses, the means for adjusting to such new legislation as it arises. One way would be for us to work together in technical areas. Perhaps, a better way would be to try to anticipate what future such legislation might cover and by making changes within our own businesses to obviate the need, real or apparent, for the passage of this legislation.

[The End]

PRESIDENT SEEKS LARGER FDA STAFF

President Kennedy's budget for fiscal 1963 proposes to increase the Food and Drug Administration staff by 25 per cent. In a statement accompanying his budget message, on January 17, he said: "Population and industrial growth with accompanying technological advances continue to place ever-increasing consumer protection responsibilities on the Food and Drug Administration. The 1963 budget provides for a 25 per cent increase in the staff of the agency, to permit an increase in all phases of the agency's consumer protection activities, with particular attention to health hazards resulting from the use of pesticides on food crops, and strengthened enforcement activities relating to the manufacture and sale of drugs."

Recent Developments Relating to Color Additives

By EUGENE A. CHASE

Mr. Chase, Counsel for Sterwin Chemicals Incorporated, Reports the Present Status of Food Color Additives and Outlines What He Feels Should Be Done in That Field.

THIS BRIEF REVIEW is not so much a report on recent developments, which have been relatively few, as an attempt to report on the present status of food color additives and what should be done in the coming year.

The Color Additive Amendments of 1960 became effective July 12, 1960. Under the statutory provisions, the Commissioner of Food and Drugs published a list of color additives deemed provisionally listed for food, drug and cosmetic use. At present, there are 12 FD&C colors, and certain of their lakes, provisionally listed and requiring certification of batches. There are also some 26 color additives provisionally listed, which never have been, and are not now required to be, certified. Fortunately, we no longer have to decide whether a product, such as B-carotene, is of coal-tar or non-coal-tar derivation. All food color additives, regardless of origin, are subject to the same statutory provisions and will be subject to the same regulations, as I think they should be.

What Has Been Done

As to the colors formerly classified as coal-tar, FDA has for some years been testing for toxicity—or, in reverse—for safety. As a result of this work, eight food color additives, including all the oil-soluble colors, have been delisted and are no longer even provisionally listed or certifiable. I am not, at this time, discussing these delistings or

the possibility of petitioning for the relisting of some of these colors, except to point out that there is no reason why those color additives, which do not fall under the ban of the Delaney clause, may not be again listed with appropriate tolerances.

The safety status of the 12 remaining FD&C colors, as shown by FDA testing (which may have changed in the short time since I have checked with FDA) is as follows:

Testing completed, with no apparent problems: Blue 1; Citrus Red 2, for its permitted uses; and Yellow 5.

Work about complete, with no indicated problems: Blue 2 and Green 3.

Work to be completed in 1962: Greens 1 and 2.

Work started November, 1960, with results available in 1963: Red 3 and Violet 1.

The remaining three colors—Reds 2 and 4 and Yellow 6—have been on test for over four years with no problems to date. Dog studies are being continued on these colors until 1964 for methodology and not for suspicion of toxicity. It is hoped that the results of these seven-year dog studies will establish that a maximum of two-year animal testing will adequately qualify colors for listing. Such testing is terrifically expensive, and anything that can be done, consistent with the protection of the public health, to reduce its time and cost should be done.

FDA has also made some studies of the reaction products of these colors. To the best of my knowledge, FDA has not made exhaustive studies on the other 26 color additives, ranging from alkånet to xanthophyll, which are provisionally listed under Section 8.501(e) of the regulations.

There is not a single one of the foregoing 36 or so colors permanently listed, and the provisional listings expire on January 12, 1963, unless the Secretary finds that a further extension of time is necessary. However, one other color additive has been listed for food use exempt from certification. This is a bit of an oddity. It is dried algae meal for use in chicken feed to enhance the yellow color of chicken skins and egg yolks and to supplement the vitamin A content of feeds low in natural carotenoids. This is far-out from what we had in mind when we started to draft color legislation, but I suppose it is properly in the color additive picture.

What Should Be Done

The proposed definitions and procedural and interpretative regulations under the Color Additive Amendments were published in the *Federal Register* of January 24, 1961. Many comments of interested persons were presented. I believe that the final regulations are still under administrative consideration, with, perhaps, some lack of unanimity.

Accordingly, at the moment, we can only rely on the proposed regulations. Section 8.17 provides that, absent a petition, the Commissioner may list a color additive by appropriate regulation. Section 8.50(a) provides that a food color additive petition shall be accompanied by a deposit of $3,000. I just don't believe that the Commissioner is going to list many colors on his own initiative.

Really, though, the fee is not the determining factor. Section 8.4 of the proposed regulations, which, I understand, will appear practically unchanged in the final regulations, calls for much more than the toxicity—or safety—studies carried out or being done by FDA. The Certified Color Industry Committee is meeting shortly to determine procedure for filing petitions for the listing of the coal-tar color additives. I am sure that industry will be permitted to refer to and incorporate the work done by FDA. However, the color industry must supply additional data, including analytical methods for determining the quantity in foods, reaction by-products in foods, methods of manufacture, proposed tolerances, specifications and so on. I think that the manufacturers and distributors of these colors will work with FDA to accomplish the permanent listings of these colors.

The bigger problem for users may be in the non-coal-tar color additives. In some instances where there is only one, or substantially only one, producer, the preparative petition work is in progress. I would think that work on carmine, carotene, iron oxides and some others is in progress. Some petitions for this group are in process with FDA but not yet formally filed.

There are some products which are technically color additives, which, because of their nature, the Commissioner may list on his own initiative. I guess at things such as beet juice, riboflavin and calcium carbonate, and perhaps caramel, which is GRAS, but still required to be listed as a color additive by regulation. I suggest inquiry by producers and users of FDA as to the status of these non-coal-tar color additives and the procedures for permanent listing, so that duplication may be avoided. In this field, I particularly call your attention

to Section 8.18 of the proposed regulations. All food color additives, whether previously classified as coal-tar or non-coal-tar, will require petitions for listing, unless listed on the Commissioner's initiative. Those petitioners wishing exemption from certification must include the requirements of Section 8.18 in their listing petitions.

In the miscellaneous field, I mention Mr. Kirk's comment last December 12, that the time extension for carbon black and titanium dioxide under the Food Additive Amendment has no significance for us because both will require color additive clearance. You have all seen the House Bill, HR 1235, to delete the exemption of color declaration on labeling of butter, cheese and ice cream. And last, we have already had two seizures under the Color Additive Amendments. The first was coconut oil colored with Yellow 4; the second, cake mix sets colored with Red 1. Neither, of course, is a permissible food color additive today.

In conclusion, I see no insurmountable problems in the food color additive field, but I think that an active program is necessary for many of us to bring about a full and rapid compliance with the law.

[The End]

"ROYAL JELLY" SEIZURE UPHELD

Food and Drug Administration seizure of Jenasol tablets, a product containing royal jelly, on misbranding charges, has been upheld—but on grounds which may be narrower than the FDA had hoped for. The labeling claims challenged by FDA were numerous, including: increased sexual vitality; relief from irritability, headaches, insomnia and depression; alleviation of the ills of old age; extension of life span; and normalization of the growth of under-developed children.

The court first held that in order to meet its burden of proof, FDA had only to prove that some—not all—of the challenged claims were false or misleading, pointing out that government evidence challenging some claims (effectiveness in treating headaches, tired eyes, and convulsions) "was not even contradicted by claimant." Reviewing conflicts in testimony as to the validity of other claims, and noting that "all of claimant's evidence related only to the efficacy of royal jelly in the fields of pediatrics and gerontology," the court reached the final conclusion that "the labeling, when read as a whole, is misleading." It also held that leaflets shipped separately to the distributors, who assembled them in sets and delivered them to purchasers or prospective purchasers, was "labeling" for purposes of the Federal Food, Drug and Cosmetic Act.

FOOD DRUG COSMETIC LAW REPORTS—*47 Bottles of "Jenasol R. J. Formula '60' * * *"*, DC N. J., ¶ 7698

Current Consumer Problems

By PERSIA CAMPBELL

Dr. Campbell Is the Chairman of the Department of Economics of Queens College, Flushing, New York. The Author Comments on the Function of the Consumer in Relation to Foods and Drugs.

MAY I FIRST MAKE IT CLEAR that I am not here as a "self-appointed consumer representative," whatever that means. At the recent Grocery Manufacturers of America convention in New York, several unflattering references were made to such people, whoever they are. For my own protection, let me say that I am here as a professor of economics and by invitation. Let me hasten to add that I very much appreciate having been invited to participate. I was glad to join in honoring the Food and Drug Administration at last night's dinner. I have a lively sense of the importance of the food industry and further, on a different level of interest, I am convinced that in the challenging and complex future, there must be closer contacts between the universities as centers of learning, and both government and business as centers of action.

I spent a day last week at Western Reserve University as a participant in an informal seminar arranged with a group of business executives; I found the experience very illuminating. I am taking your time today because I think there is an important point of view that should be brought to your attention, which you might otherwise overlook and which I hope you will allow me as a professor who has a special interest in, and concern for, the consumer position in our society, to present. And though I know this is a mixed audience, I shall address my remarks, particularly, and with respect, to members of the food industry.

Lack of information among consumer-oriented spokesmen at recent Congressional hearings on factors that underlie industry deci-

sions, has been a major complaint among industry representatives. I have heard discussion of the need for better communication with the consumer public in order that the industry "image" might be polished up. According to the *Modern Grocer*, this image "has been under grave assault in recent months." It does seem rather odd that with all the facilities of the mass media at industry's command, and with the enormous sums spent through these channels, there should be such present emphasis on the failure of communication. But I do not think that even a massive public relations campaign to inform the consumer public on the industry position will solve the "current problem." It goes deeper than a failure to communicate a position. I have read with interest the account given by one of the speakers at the recent Grocery Manufacturers of America convention about the industry-wide campaign undertaken a year or two ago with respect to chemical additives. The campaign, it was explained, was developed to convince the consumer public that questions raised with respect to the possible health hazards in certain chemical additives were "spooks—raised by small but clamorous groups of food faddists." As a result of the campaign, according to the speaker, these "spooks . . . were firmly laid to rest by a food industry which banded together for a counter-attack based on truth." Now you know, as I know, that this account misses the central point of the story. The real reason why there has been less public concern over such hazards—recognized as such, by the way, by some of our most eminent public health experts and regulatory officials—was the final success of a legislative struggle to require food processors and packers to test new chemical additives for safety, before use, to the satisfaction of the Food and Drug Administration. There is public confidence in the integrity and ability of the FDA to deal with whatever hazards may exist; the general support expressed last night for the administration gives hope that it will get adequate appropriations for the job.

Improvement of Attitudes and Relationships Needed

I mention this incident only because I think that another massive campaign to inform the consumer public on the industry position with respect to various packaging and related practices will also miss the point unless it takes into account an underlying problem. This problem is one of attitudes and relationships that need improving, but will only be improved with a clearer recognition of function—

industry's function on the one hand, and on the other the consumer function in the economy.

Until the consumer function is recognized and respected there will be a problem of relationships more significant than any particular complaint about slack-filled packages or "packaging to price." With continuing product and merchandising innovations, as each member of the industry tries to obtain and maintain a competitive position, other reasons for explosive complaints will undoubtedly develop, year after year, unless we can solve this basic issue. So in addressing myself to the subject assigned to me on this program, namely "consumer problems," I shall focus my comments on the nature of the consumer function and how to get recognition for it; I shall try to establish better communication upstream in the marketing channel, though of course without the elaborate facilities available to industry in the reverse direction.

At the Grocery Manufacturers of America convention, one speaker after another reiterated that "the consumer is boss." Apart from the fact that "boss" has now become a dirty word in our vocabulary of public affairs, I urge you to examine more closely your interpretation of it. The consumer function in the economy cannot be measured by particular sales statistics; nor is it that of a robot to be programmed for particular behavior responses.

The family gets income in exchange for some one's labor. The consumer buyer for the family has the responsibility of exchanging this income to best advantage, *within the limits of market conditions*, for goods and services that will satisfy the family's economic wants. The limiting factor of market conditions is an outcome of the *production* process. The individual consumer at the market has little power to alter them, other than perhaps to get an adjustment for a particular complaint. If the aggregate consumer veto is large enough a particular product or service may be withdrawn from the market. But there is plenty of evidence to show that the consumer cannot, through market action alone, establish the positive conditions necessary for the competent exercise of the consumer function—and which are also necessary to give the responsible businessman a competitive advantage so he can resist a downgrading pressure on trade practices in line with Gresham's law.

For the optimum use of resources to provide a secure material foundation for our democratic way of life we need a working partner-

ship between industry and consumers, at least to the extent of recognition and exploration of mutual problems. Such a partnership must be based on mutual confidence, if the foundation is to be soundly built. There is a regrettable tendency among some industry representatives to regard all consumer complaints, publicly expressed, as the work of "publicity hounds" or "faddists." Not only consumer-oriented leaders of opinion, but also food and drug and weights and measures officials at annual conferences, and, I am told, some retailer representatives, had been trying to draw the food industry's attention to a rising level of consumer frustration and even resentment with certain questionable practices in the "marketing revolution," for some time before public pressure led to the recent Congressional hearings. These hearings were followed by an avalanche of mail that swamped not only the Congressional representatives but also the consumer-oriented spokesmen.

This public disclosure of consumer discontent in what should be a satisfying state of relative affluence, is said to have led in a number of instances to a rapid review of certain business policies and practices. But I hear that at least some of this activity was undertaken in a grudging mood and with the attitude of "throw them something to keep them quiet." This really reflects the basic problem I am trying to bring to your attention. The existing system of market research and market testing is obviously not adequate to establish and maintain the public image desired by responsible businessmen not only for a particular product but, in the broad perspective of public affairs, for the satisfactory performance of industry's economic function—to organize resources for satisfying consumption, with profit the reward for service. "Service" is the key word. This is a matter for "top management." In my opinion it is to the advantage of responsible businessmen, and not a frightening prospect, to have a clearer recognition of the consumer function, and of the development of a legitimate consumer interest with respect to that function. Further, in our modern structured society, organization about the consumer interest is necessary if we are to have effective representation of a consumer point of view both in relations with industry and in the development of government economic policy. There is, as I have already suggested, need for a bargaining partnership in the rapidly changing economic enterprise. And there is need for a central focus on the consumer interest within the structure of government itself; for however loudly the principle of *laissez-faire* is proclaimed, we all

know that government action, at all levels of government, affects the economic position of all parties at interest.

On Government Intervention

Businessmen seek government intervention in situations in which they believe intervention will be of benefit to them. And consumers seek aid and protection in situations in which they think they cannot otherwise perform their function adequately, but with less effect than businessmen because they are mainly unorganized and act sporadically. The job before us is to find the proper framework of law within which initiative and bargaining can develop most advantageously in the public interest. Some industry representatives at the Grocery Manufacturers of America convention invoked Adam Smith and *laissez-faire* (and, sad to say, Adam Smith is usually misinterpreted), but let me also remind you of a statement made at the convention by Alma Lach of the Chicago *Sun-Times*. She was emphasizing the spectacular developments in the food industry. "When people talk to me about the 'good old days'" she said, ". . . I first ask them if they would like to go back to drinking unpasteurized milk, and then inquire if they would like once again to eat meats that carry no government stamp of approval." The food industry is too big to be afraid of bogies.

Beofre further examining the nature of the consumer function, let me point out that the term 'consumer" is used generally with either one of two different meanings. The broader meaning relates to the individual in the process of making final use of goods and services—it conjures up a picture of the family round the dinner table enjoying the fruits of labor. The narrower meaning relates to the consumer in the process of spending family income at the market in the broadest sense of "the market." Neither of these two meanings covers an increasingly important part of the consumer function, namely the process of want-formation in a high productive economy such as ours. This process of want-formation goes on all the time in some mysterious way; it extends, of course, beyond the economic sphere. We are told that in many low-income countries, the level of wants is rising faster than the capacity of the economy to satisfy them; the pressure of unsatisfied wants tends to develop revolutionary attitudes.

Our own situation is very different, but it has its own problems. There is an expanding range of discretionary income from which

to satisfy an increasing number of wants developed in response to a multiplicity of stimuli. And there is an incessant pounding for attention by alternative possibilities for want satisfaction competitively offered on "easy terms" at "bargain prices" and through all media of communication from some of which it is impossible to protect one's privacy. Patience, energy and time remain limited, though some expansion of effective time has been made possible by household gadgets and convenience foods. I am not advocating a return to the simple life, whatever that is, and it seems rank stupidity to complain of a state of plenty. But we must recognize that it has led to a tendency on the producer side of the market, to "oversell." And on the consumer side it has necessitated the making of discriminating choices among many wants, new and old, in a continuing process of adjustment for individual members of the family, at different stages of the family cycle. It has called also for difficult choices, within the limits of purchasing power, among an extraordinary range of goods and services, new and old. The present state of our affluent society has in fact created a certain brittleness in buyer-seller relations that has to be recognized. I am told that in the present supermarket there are some 6000 to 8000 items jostling for a recognizable position, and that within a few years there will be from 20,000 to 30,000. What a marvellous and terrifying prospect for the consumer who wants to do a good job buying food for the family. And food represents only from 25% to 30% of average expenditures, with the percentage declining, as Engles predicted, on a rising level of income. Increasing numbers of consumers are coming to recognize that they must have more meaningful information for the proper performance of their function, and even more protection.

The function of the consumer buyer is to spend the family income in such a way as to maximize satisfaction of the family's wants, taking all related matters into consideration (so far as they can be recognized). Since the end is satisfaction, a real but elusive concept, there is no quantitative measure of consumer competence, no dollar measure as in a system of business accounts. A balanced family budget is no proof in itself of competence, in terms of the optimum satisfaction of wants, though an unbalanced one raises a warning flag. Currently, in the aggregate, American consumers are spending some $350 billion per annum, an enormous job for which, by and large, they have had very little formal education. Manufactures and distributors engage specialists to do their corporate buying, and within limited fields. But

the consumer-buyer, the buyer for the family, remains an amateur in selecting among the total range of goods and services that make up the ever-changing expenditure pattern, and, again, within the limitations of time, energy and patience.

In their *Principles of Marketing*, Backman, Maynard and Davidson explain:

> "The more the retail selling and service functions are curtailed, the greater becomes the task and responsibility of the consumer as a buyer. While there is a substantial amount of prebuying stimulation in the form of aggressive retailer and manufacturer advertising and sales promotion activity, the number of items competing for consumer attention is so vast and diverse that the ordinary person must play an extremely active role in making the purchase that satisfies his want."

In "buying to satisfaction," the consumer needs from the seller meaningful and easily recognizable information about the particular product and service, useful in the process of selection; where this information is not adequate for an intelligent decision on comparative values, then the consumer also needs the guidance of effective standards, and tests against standards, with respect to terminology (whether for price, quantity or quality), for identification and for performance ratings. There may also be need for protective support from regulatory agencies against harmful practices that adversely affect the consumer interest. Of course we know that many consumers are uninformed and gullible and cannot perform their function well under any circumstances; nor can they contribute to the cause of making honesty pay. This is one of the consequences of our failure to provide effective consumer education. Government and educational institutions have contributed research, information and education to farmers and small businesmen to improve their performance as producers, because they operate on a small unit basis and cannot provide these services effectively for themselves. Relatively little has been done for the small family unit in its consumer capacity. Nevertheless we must do the best we can to encourage consumer competence in the interest of the family and also of the economy as a whole. And in the interest of democratic ethics.

Theoretically, the consumer, in a relatively competitive market, through intelligent choice, supports the honest and efficient producer and guides the use of economic resources for optimum social advantage. But as pointed out above, the individual consumer at today's market cannot function effectively through the market vote alone. Organization about the consumer interest and representation of that interest

are necessary for a dynamic economy functioning within the framework of law. The purpose of law in a democratic society is to channel the forces of change in such a way that they will fructify and not destroy; it is an instrument, not a taskmaster. In the new economy, consumer sovereignty takes on a larger meaning than might be inferred from the phrase, "the consumer is boss"; it calls for greater responsibility; it implies new relationships. This is the main point I want to bring to your attention today. I do so in the hope of a more cooperative solution to emerging problems than the kind of crisis attack we have recently experienced.

Consumer-Industry Relations

Let me take advantage of your patience a few moments longer to apply these general remarks more particularly to consumer-industry relations in the food field.

Yours is a basic industry and it must be a source of much gratification to you. I can understand why your first reaction to recent consumer criticism is to want to throw a heavy book of facts at the ingrates. We do not know, or at any rate I do not know much about how the modern consumer feels in a general way on the many-faceted subject of food for the family. More is known about consumer reaction to particular items as for instance the virtues of different pancake mixes. Certainly—and fortunately—in our society, food does not have to be thought of in terms of survival, but as a source of health and appetite pleasure. I was glad to read the testimony of one of the industry witnesses at the packaging hearings in which he urged: "Let's get back to selling food again. Let's sell sound grocery-store nutrition. Let's talk about flavor, ripeness, proteins and vitamins—not free trips around the world, or premium silverware, or the overworked "cents-off" deals . . . ."

Shopping for food is a different experience from shopping for other commodity categories. It is done at relatively frequent intervals, in relatively small amounts, and for the most part by the housewife in the midst of a multitude of other chores—though men are now showing up in larger numbers than formerly, at the supermarkets. The results of food shopping are subject to quick and continuing appraisal by members of the family, for whom food is part of a customary routine of meals, associated often with strong emotional factors. The family's food purchasing agent may or may not be success-

ful in introducing new items or new techniques into the routine. There is no point to making a decision among frozen, canned and fresh peas if the family is fed up with peas in any form—unless they can be intrigued into trying a new pea-food innovation, with the help of the mass media, and is it worth the effort?

Of course consumers want wholesome food—food not deleterious to health; and on the positive side, they want nutritious food—they want it so much in fact that, ignorantly, they waste millions a year, we are told, on food quackery. Wholesome and nutritious food is more important than package shapes and sizes though it may not seem to be so from superficial day-by-day reactions. A threat to the wholesomeness of food, or what is believed to be a threat, creates a crisis situation. But consumers, generally speaking, assume that government is taking care of this matter. Some things come to be taken for granted, like the purity of the water supply, until an accident occurs or a new hazard appears. During the long legislative struggle for more effective control over the use of chemical additives, it was surprising to me how many people found it hard to believe that the government did not already have authority to require protesting before use. And may I remind representatives of the food industry who resent what appears to be consumer ingratitude in the present packaging controversy, that the image presented by the industry during the additive-control struggle, was not itself very bright, indeed it appeared to be obstructionist. No doubt various amendments to the changing legislative proposals were useful or even practically necessary. Nevertheless, and I hope you will not be offended—I found it difficult to understand why, as a matter of good public relations, you allowed yourselves to get into what certainly appeared to be a negative or feet-dragging position on an issue which involved certain hazards, however limited, to the food supply—admittedly an emotionally charged subject.

With respect to the positive aspects of food as nutrition—which is drummed into us daily, inescapably, through the mass media—I want to express my personal appreciation of the public support which the American Medical Association is now giving to the Food and Drug Administration, in its effort to help protect the consumer public against food quackery, by moving more positively against the food quacks. I hope that the various elements of the food industry will join more actively in the attack. If the consumer public, with such powerful support, could relieve itself of this wolf in sheep's clothing,

it would be in a better position to appreciate the important contributions made by responsible members of the food industry to the rising level of public health—by "sound grocery-store nutrition."

Certainly the food industry has made remarkable contributions in the rapid development of convenience foods, of new products and new uses of old products—built-in services, with product innovation and product differentiation. This development has lightened kitchen chores, given the housewife more leisure, and in many instances brought a better and more attractive product to the table. The package recipe becomes the modern cookbook. It is probably true that consumers do not realize how much research and planning has gone into this aspect of progress. It hasn't just happened. I have no praise for the good old days and rather wonder at an apparent tendency for escape, whenever opportunity offers, to primitive forms of backyard cookery. However, there is a possibility that product differentiation will get to the point—perhaps in some instances the point has already been reached—when this form of progress ceases to have any real meaning for the consumer and may even become a source of confusion. When, for instance, there is little essential difference among the products themselves, greater emphasis has to be put, for competitive advantage, on the promotion of brand names and package designs to attract interest. Product progress then becomes part of the "packaging problem," and like an aching tooth, the problem takes over.

"Packaging Problem"

I am sure you have all read reams of testimony on the "packaging problem." It is of course part of the great merchandising revolution. Consumers deserve some credit for the readiness with which they have taken over some of the traditional merchandising functions. It is in this take-over that they have found themselves confronted by long lines of "product-personalities" who are not as cooperative as they might be in facilitating competent performance of the expanded consumer function—indeed, not to mince matters, their lack of cooperation has, in some instances, become a public abuse.

One aspect of the packaging testimony that specially interested me was the different positions taken and arguments presented by representatives of different segments of the food industry on particular issues under discussion. A package designer tells us that in the modern competitive struggle for attention among different products and different brands, among national and distributor brands, the front

panel of a package must have uncluttered space to allow for instant recognition of an advertised name; but the retailer wants at least a small white spot on which to mark his price. We are told, on the one hand, that what the consumer is interested in is not weight designation but the number of servings; however it is not considered practical to set up standards to establish when a serving is a serving. We are told that consumers prefer a reduction in quantity to an increase in price but at the same time we get an industry warning that recipes are based on designated quantity. We are told that slack fill results from a natural settling process—but admittedly not in all cases; and standards of fill are objected to as possibly interfering with business initiative. Uniform package sizes with different product densities lead to fractionalized weights; but the customer should be intelligent enough, it is said, to take pencil and paper along as a shopping tool—the thought of consumers blocking the Friday evening aisles while making their calculations must give the supermarket manager a nightmare! The consumer, we are told, can take care of himself through trial and error—but how many tries and how many errors are considered reasonable is not indicated. The consumer is not misled into thinking that the king sized half-quart is more than a half-quart (then what's the point?). Or he is a sucker and deserves his fate. And so on.

The new situation in which the product must sell itself, supported by whatever promotional advertising it is given, and any advantageous shelf position it is able to obtain, obviously creates difficulties for different segments of the food industry. And also for the consumer. I am not going to suggest to you now what particular information, in what particular form, the consumer needs to make the best buy—or will take advantage of. In the continuing process of economic change, and in merchandising, change is very rapid, new situations and conflicting interests continually emerge; there can be no definitive solution of resultant problems. This is why I say that the present controversy goes deeper than a matter of shapes and sizes. And why I am suggesting new attitudes and new relationships among the functional groups and also with the appropriate agencies and levels of government—though this fragmentation of political authority is a complicating factor. We need social innovation as well as—even more than—product innovation.

During the years 1956-1958, far-reaching laws were passed in New York State to regulate the rapidly expanding credit industry. These

laws were developed through a process of organized negotiation between representatives of all parties involved on the initiative of the consumer counsel to the Governor. The end-product was accepted unanimously by the various members of the negotiating group and also by the legislature and has since become the basis for regulation in a number of other states. I suggest the same approach be made to the less complicated packaging problem. If the food industry, powerful and responsible, will recognize and respect the consumer function, as broadly defined above, I am sure a satisfactory solution can be found for mutual advantage in the public interest. **[The End]**

HEW RELEASE

The Food and Drug Administration announced today institution of a criminal contempt of court action against the Electronic Medical Foundation, San Francisco, California, and Fred J. Hart, its president.

The action charged the Foundation and Hart with violation of a 1958 court order prohibiting any further distribution of 13 types of medical devices which had been claimed to diagnose and treat hundreds of diseases based on "emanations" supposedly given off by a drop of dried blood sent in on a piece of sterile paper.

Practitioners who mailed in blood spots taken from their patients received, for a fee, a diagnosis blank filled in with the diseases the patient was supposed to have and the recommended dial settings for treatment with the Foundation's "electronic" devices.

Papers filed in the Federal District Court in San Francisco charged that Hart delivered one of the banned devices, called the "Short Wave Oscillotron" to an out of state practitioner in July of this year. The machine produces a short wave radio frequency, that is of no therapeutic value, FDA said.

Investigations showed that the diagnostic service offered by the Foundation was incapable of distinguishing the blood of animals or birds from that of the living or the dead. Blood submitted from an amputee resulted in a report of arthritic involvement in the right foot and ankle which the man had lost several years before. Blood from a rooster resulted in a diagnosis of sinus infection and dental caries.

Extensive test of the treatment devices showed that they were also worthless, according to the agency. The names of the 13 machines banned by the 1958 court order includes a regular push button shortwave oscilloclast and a sinusoidal four-in-one shortwave oscillotron. In addition to these machines the decree banned interstate shipment of "Blood Specimen Carriers" for use in the diagnostic machine, the Radioscope, which was maintained at the Foundation's offices in San Francisco.

Hart is also President of the "National Health Federation," an organization which shares offices with the Electronic Medical Foundation and is devoted to such causes as defending use by drugless healers of dietary foods and devices of unproved efficacy, opposition to fluoridation of drinking water to prevent dental caries, and promotion of worthless cancer remedies such as the Hoxsey cure.

Panel Discussion of Questions Submitted to the 1961 FDA-FLI Conference

A Question and Answer Panel Session on the Afternoon of November 28 Concluded the 1961 Joint National Conference of The Food and Drug Administration and The Food Law Institute, Inc. The Panel Discussed Food Additives, Labeling and Other Unresolved Problems. Mr. Franklin M. Depew, the President of The Food Law Institute, Was Moderator of the Session. (Answers Offered by Members of the Panel During This Session Do Not Necessarily Represent the Views of Other Members of the Panel.)

MR. FRANKLIN M. DEPEW: I take this opportunity to acknowledge, for all of us in The Food Law Institute, the many courtesies extended to us by representatives of the United States Food and Drug Administration on the occasion of this 1961 conference. I wish particularly to express my personal pleasure in working with Assistant Commissioner Winton B. Rankin to organize the program of this conference, and finally, I voice the thanks of all present for the fine contributions made by the speakers on our program.

Permit me now to offer a brief report on FLI progress during the past year which has culminated in this important meeting. I know that all here appreciate the educational value of the FLI program and would like to see it expanded. While our budget does not as yet permit an expansion of our program, I can report that we should soon be able to stop using our reserves. Our membership committee, under the chairmanship of Mr. Edgar J. Forio, has almost doubled our membership, and Mr. Lee S. Bickmore, the new chairman, is launching a new campaign which I am confident will achieve our membership goal. Most of you here, perhaps all, represent member companies. If your company is not a member, your sympathetic recommendation of membership is solicited.

I call your attention to the course of instruction in food and drug law that will be given next spring at George Washington Uni-

versity. The instruction is given by Mr. William W. Goodrich and by Mr. Alan H. Kaplan, a former FLI fellow. I recommend this course to lawyers and others interested in these laws, who are located in the Washington area.

The FLI also sponsors courses in these laws at New York University, the University of North Carolina and the University of Southern California. Those of you from the West Coast will be interested to learn that we are working with Stanford University to prepare a symposium on this law in the near future. At the University of Southern California, an important lecture will be given next spring by a food executive on the history, social significance and public policy of the food and drug law. Industry representatives will be welcome at both of these meetings.

The manuscript of the new Kleinfeld book on the Federal Food, Drug, and Cosmetic Act has been delivered to the publisher and should be available soon, and we are planning to publish other books in the FLI series in the near future.

As you have been previously informed, the proceedings of this conference will be reported in the FOOD DRUG COSMETIC LAW JOURNAL. If you do not subscribe to this important journal, I recommend it for your consideration.

As president of the FLI, it was my privilege to testify in support of an expanded FDA budget before the Senate and House Appropriation Committees. I there pointed out the effectiveness of the FDA in the consumer protection field, and I supported the continuance of the career system for all FDA personnel. The FDA needs increased funds to properly and effectively carry on its valuable function.

We will now proceed with the question and answer panel. I don't think any one up here needs introduction. You've seen them all here before, so I will proceed with the questions.

I first have a question for Mr. Clark:

I understand that there are household products which contain a very poisonous material as an ingredient, but the final product has never caused any trouble. Must such a product be labeled under the Federal Hazardous Substances Labeling Act?

Mr. Clark: The Federal Hazardous Substances Labeling Act deals with the final product as used in the household and even though one of its ingredients in a pure state might be very toxic, it would be the characteristics, either the toxicity, the irritancy, or some other

hazard of the final product that would control, and not those of its ingredients. It is helpful in arriving at an opinion as to the proper labeling of the final product to know the properties of the ingredients but it would be the hazards of the finished product that would control.

Mr. Depew: A question for Dr. Banes: Is there a relationship between the chick edema factor and free fatty acid? If there is, what is considered a maximum level of safety for free fatty acids in cooking oils?

Dr. Banes: The only relationship we know of between the chick edema factor and free fatty acids is that certain free fatty acids have been found to be contaminated with chick edema factor. That's also true of certain products from free fatty acids, that is, synthetic esters. As to the level of free fatty acids in foods, I can't make a general statement. It would depend on the constituents of the acids. If a fatty acid has been found to be contaminated with chick edema factor, it should not and cannot be used under the regulations in preparations for human consumption.

Mr. Depew: A question for Mr. Roe: Would a representative of the FDA comment on what information is available as to the risk of ink migration into a product from roll stock printed cellophane?

Mr. Roe: The question of printing inks on labels has been considered; it is necessary to consider them from time to time under Food Additive petitions. The question of whether the ink, if in contact with a food in the container would migrate into the food and place any harmful ingredients in it—I don't know that I can make any general statement as to how that can be evaluated other than applying the tests that we have suggested for checking for migration of the various ingredients in or on packaging materials. It is simply a question of fact whether under the usage and under the contact with food there would, in fact, be any migration.

Mr. Depew: Mr. Kirk: Since mineral oil N. F. meets N. F. requirements, does this mean that mineral oil will be permitted in food for man and feed for animals?

Mr. Kirk: Mineral oil is classed as a food additive and any proposal to use it in or on food would call for an appropriate Food Additive Petition and subsequent regulation. The fact that the product is N. F. would be only the starting point.

Mr. Depew: I have a very interesting question here Mr. Goodrich: Are not closed hearings on changes in regulations offensively

dictatorial? I cannot help contact the closed hearings used in Federal regulation changes with recent changes in air pollution regulations in the District of Columbia where about a dozen scheduled speakers representing all sides of the question were heard, unscheduled comment was then asked for and several speakers were heard. Finally, we were told that we would have a week to submit further written comment before the testimony would be evaluated. Why are not procedures such as this used in establishing and changing FDA and pesticide regulations?

The final decision . . . (this is a note to the question) the final decision was still made in chambers but at least there was available a broad range of stimulating and cross-fertilized opinion.

Mr. Goodrich: We stopped beating our wife a long, long time ago, and we can start off with that answer, I think. We do have formal procedures for all of our rule-making activities, some more formal than the others, as I pointed out in my discussion yesterday. In our pesticide regulations, we are bound to start with a Notice of the Filing of the Petition. We then come out with a tolerance. It is subject to objections; then if the objections are taken soundly, they are followed by a public hearing, with judicial review. In the case of some regulations, the law does not require a hearing. That was true with the initial regulations for the Federal Hazardous Substances Labeling Act. We had a big meeting down in this room; it didn't satisfy everybody, but it was in addition to the approximately 500 written comments in some depth which we received, and which I might say, all received consideration. What was the word—cross-fertilization of ideas—we received plenty of this. We came out with the final regulation after all this study. But of all the Federal laws, when you talk about one that doesn't have adequate public proceedings, you picked a very bad one under the Food and Drugs Act. This was passed in 1938, just after Henry Wallace had decided the famous *Stockyard* case. Congress wrote in the most formal type of procedures. We lived with those until the Hale Amendment was passed a few years ago, which did nothing at all to take away the formalism in those areas where there was a real controversy. We have that today, and anyone who thinks we do operate in a Star Chamber type of activity is simply unfamiliar with our procedures, and I invite them to visit our Hearing Clerk's office to look at the proposals, look at the comments, and see what was done with them. I hope that's not too long an answer for such a short question.

Mr. Depew: A question for Mr. Clark: If a competitor has obtained an exemption from the labeling requirements of the Federal Hazardous Substances Labeling Act, does it also apply to us? How will we find out about such an exemption?

Mr. Clark: Well, I assume the question means a product similar to the one on which an exemption was obtained. We need experience in this exemption field but it will be our purpose, wherever we can, to give exemptions on the broadest possible base rather than on specific products although we may have to do that in some instances. Such exemptions, as Mr. Harvey stated yesterday, will be published as Regulations in the *Federal Register*. There will be no publication of petitions for exemption which have been denied. Those will be between Food and Drug Administration and the petitioner, but there will be under Section 191.63 of the Regulations, publication of the exemptions.

Mr. Depew: A question for Dr. Zapp: One of the speakers yesterday afternoon, I believe the last one, implied that the protection the new labeling law is going to afford against dangerous home products should be balanced against what it will cost industry to label its products satisfactorily. Does industry really support the view that human lives should be balanced against money in this way?

Dr. Zapp: Well that's almost as bad as the question that was asked Mr. Goodrich. It certainly does not represent what I said yesterday. I pointed out that industry actually has been supporting cautionary labeling of products for a great many years, that it wanted, backed and assisted in getting the Federal Hazardous Substances Labeling Act passed, so I think that that part of the thing is quite clear. What I did say was that the regulations implementing the Federal Hazardous Substances Labeling Act have proposed a different format of labeling from any that is in use at the present time. It isn't that they require different words or even a stronger statement of cautionary information but rather the placement of it in a certain way on the front panel and set off in certain specific ways. I pointed out that there is no background of scientific fact or historical fact that would say that this new format will accomplish a purpose better than any existing industrial label at the present time. This is a matter of opinion. Maybe it does. But I also said that if industry is required to change the labels on all existing packages, or virtually all existing packages by February 1, 1962, this will require the expenditure of millions of dollars and many man-hours—the cost of which is ulti-

mately going to be borne by the consumer. And my only question was whether this type of expenditure relating to the existing, already labeled and packaged products, is going to return value for the money expended.

Mr. Depew: Another question for you: Does the industry's concern over labeling of hazardous substances, which I understand existed before the new law, stem from humanitarianism or from the danger of suits by people who are injured? (Laughter)

Dr. Zapp: I must not live right! This kind of question! However, I note that the questioner recognizes the fact that industry does have a concern with cautionary labeling. Now, it seems to me the rest of the question is something like this. I note that you go to church. Do you do this because you believe in God, or because you're afraid if you don't you'll go to hell? It's the same kind of question, isn't it? And I don't think there is any answer that can be given to it. When you get beyond the fact the industry historically has been concerned, and then inquire into the motives as to why they're concerned, there isn't any one answer and certainly there is no one answer that I can give. I would say that I find humanitarians among industry and I find people who are compelled by laws just as you find in any other group, and I think that if you try to get an answer to this question, you would find that there are all sorts of motives involved. But the fact is that industry has had this concern.

Mr. Depew: A question for Mr. Rankin: Mr. Cribbett said that if necessary FDA will establish tolerances for radioactivity in food. How can you do this in view of the Delaney Clause of the Food Additives Amendment?

Mr. Rankin: The Food Additives Amendment does not apply to materials that get in accidentally as from radioactive fallout. There was some debate when the Amendment was before Congress as to whether the Congress should strike from the law the provision dealing with accidental contamination. And the Congress decided it would leave Section 406(a) in the law to take care of accidents. Clearly the food grower, the food manufacturer, has no control over the amount of fallout reaching his product, it is not an intentional additive so far as he is concerned, it is not subject to the Delaney Clause.

Mr. Depew: A question for Dr. Campbell: I would like to hear a further discussion by Dr. Campbell of the approach that she suggests to the packaging problem. Does she suggest round table negotiations leading to new federal laws to regulate packaging?

Dr. Campbell: I suggest round table negotiations. Whether necessarily they'll lead to new federal laws or not depends on what came out of the general discussions. I'm not talking so much of negotiation as discussion of many of these problems. The points of view of industry and the consumer should all be taken into account in terms of the greatest advantage—public advantage.

Mr. Depew: Mr. Rankin: Why is the government so concerned about fallout when the levels are so low, as described by the speaker from the Atomic Energy Commisson?

Mr. Rankin: I believe the answer to that was covered both by Dr. Lough this morning and by Mr. Cribbett yesterday morning. The position that the federal government takes, and this is a position recommended by the Federal Radiation Council and adopted by the President, is that since we cannot prove with experiments that have been conducted to date, or experiments that are foreseeable, either that minute amounts of radioactivity do cause definite harm or that they do not cause definite harm, the prudent course of action is to conclude, to assume that we will get harm from small amounts of radioactivity. This presumes that every increase above the background radioactivity is going to create difficulty, some problems for the present generation and other problems for future generations. It is prudent then to take all measures possible to keep radioactivity to a minimum, to keep from increasing the background that we are exposed to anymore than is necessary.

Mr. Depew: Is the FDA ready to agree that the Delaney Clause is unworkable and to recommend its repeal?

Mr. Rankin: Someone suggested from my left that I could answer that with one word, but I'll take a few more words than that. We do not agree that the Delaney Clause is unworkable; on the contrary it is quite workable. That's what's causing some people some difficulty. It's working and the shoe is pinching a bit. In the second place, we have announced repeatedly that when the scientific evidence is available to show us that we can safely establish a tolerance for a substance that is found to induce cancer when fed, we will then be willing to recommend to the Congress that the Delaney Clause be changed. Until that time, we're not prepared to recommend a change. Except for animal feeds we are prepared to go along with a change that would allow a cancer producing substance to be incorpo-

rated in animal feed, where there is evidence that it does not harm the test animal and it does not leave residues in man's food derived from the test animal—the treated animal.

Mr. Depew: Would anyone else on the panel like to comment on that answer?

Dr. Oser: I'd like to comment on the workability of the Delaney Clause. When this subject came up over in Congress, the question came up about residues of stilbestrol in cattle. The record showed that the analytical method had gradually been reduced to detect very little residues but that they are unable to detect them in the cattle. It seems like something around 70 to 80 per cent of the cattle in this country were being treated with this feed. I raised the question with a Congressman. Suppose the method is further improved so they do detect it in the cattle. Will all these cattle become illegal for food uses overnight? The preceding secretary came back over and testified that they might change the method. Now that's the way it works.

Mr. Goodrich: May I comment on that? Our preceding secretary went over to the Congress and strongly supported the Delaney Amendment. He said, in terms of methodology, that he had no anticipation that there were refinements of the kind you were speculating about, and there were no plans on this. However, if he found a minute residue in the animals, it would have to be treated the same as other Delaney Amendment constituents. Now Secretary Flemming made it very plain that where a carcinogen could be tolerated in an animal's food, would'nt hurt the animal and would leave no residue in man's food, he was perfectly willing to go along with an amendment to permit it. He made it equally plain that where we found a minute residue of a carcinogen in man's food, until the people in NIH, National Cancer Institute and other scientific groups, could say that it was safe, he would have to take the prudent course and say he was against it. And no one that spoke on the Delaney Clause when it was in Congress advocated any tolerance for any cancer-producer that I know anything about. It was just a question of do we outlaw it by name or by necessary implication.

Mr. Depew: A question for Mr. Roe: If FDA is now ready to determine trillionths of a gram of chemicals, how long will it be before the government starts seizing milk because of high pesticide residues?

Mr. Roe: Well, there seems to be a sort of a double twist to that question. In the first place, the government will start seizing milk any time that it finds significant residues in it. When it comes to trillionths, very minute quantities, then I don't think that we're going to be concerned. It depends upon what the trillionth represents and what all of the factors are, but I would say that we are not looking for the smallest amounts as a basis for seizure, but we are bound, of course, to undertake seizure where we do find any residues of significance.

Mr. Depew: Another question, Mr. Roe: What is FDA going to do to reduce the high incidence of food poisoning that Dr. Slocum reported. How about bacteriological standards of purity?

Mr. Roe: Well, I think bacteriological standards of purity are one of the approaches to that problem. Dr. Slocum's division is undertaking research studies on the food poisoning organisms to evaluate all of the factors that may be involved. It will give us bacteriological procedures that will help detect the presence of food poisoning organisms and give us a basis for checking foods and removing from the market those that may be so contaminated. Bacteriological standards may be a partial help in some cases. This would depend, of course, on what our researches show, whether there are bacteria counts. That would be meaningful in terms of the toxicity or potential toxicity of the foods. Certainly bacteriology is a potent scientific tool in studying and dealing with this problem.

Mr. Depew: Mr. Kirk: When is FDA going to agree to the manufacture of fish flour?

Mr. Kirk: We agree to the manufacture of it right now. We have not taken any action to stop the manufacture of fish flour. Fish flour for human consumption made from the clean, sound, edible portions of the fish is, of course, a perfectly legal product. Fish flour made from the whole fish, which includes those portions not regarded as suitable for human food in this country may be sold for fertilizer, may be sold for animal feed, and additionally, may be sold for human food to any country in the world where the laws of that country do not prohibit it. As you probably know, we have published a proposal submitted to us to establish a standard of identity for this product for human consumption. The time for filing comments on this proposal terminated a couple of weeks ago. We have almost 2,000 comments, many of them violently opposed to the idea. People say, "I just wouldn't eat this stuff." Others say it is a wonderful thing for the

rest of the world. We don't disagree. We do have a substantial number of letters that are very frank. People write in and say, "We're in the menhaden business, we catch these fish, and we've been selling our product for fertilizer and animal feed and we think it would be wonderful for our business if you'd let this stuff be sold for human food." The Commissioner has the responsibility for reviewing all the comments which come in, and must make a decision to be published in the *Federal Register* which can do one of three things: Accept the proposal; accept it with modifications; or reject it. We're hopeful that we can get that decision, whichever one of those it is, in the *Register* very shortly. Yes, whatever decision is made will be subject, as Mr. Goodrich mentioned earlier, to the objection procedures within a specified period of time, whereby any adversely affected party may demand a public hearing. Then the decision must be based on the record of the hearing, and if someone doesn't like that final decision, he can go to court.

Mr. Depew: Mr. Goodrich: Why doesn't FDA require food packages to have a certain size type for information the consumer wants, like Canada?

Mr. Goodrich: We have a general regulation that was adopted in 1940 which we thought would get the message across. It says that the required mandatory information must be prominently placed on the panel that is likely to be displayed under customary conditions of purchase. It is one of those regulations which says what should be done, instead of what has to be done, and I'm afraid the message doesn't quite come through. We have no proposals now to fix size or placement of labeling, other than in hazardous substances and in our recent proposal on prescription drugs. We are hopeful that the compliance with the spirit of our existing regulation will put this mandatory information at a place and in size where it will be noticeable, but we do have a very active program now against inconspicuous labeling both in terms of the mandatory ingredients and in terms of the net weight. I think if anyone will look over our press releases and our experience, they'll find that much needs to be done here. Whether we'll eventually have to adopt a regulation on size remains to be seen, but, as I said yesterday, under the Hazardous Substances Labeling Act, we think we have that authority.

Mr. Depew: Has FDA—or any other agency—developed recommendations for getting rid of fallout in food?

Mr. Rankin: First, I would point out that both of our speakers on radioactivity, Dr. Lough and Mr. Cribbett, have emphasized the minute quantity of fallout that is reaching food at this time. But if we get to the place that fallout becomes a problem, there are a number of steps that can be taken. Remember that fallout is essentially a type of dust. The types of removal procedures that you use for dust can be used for fallout. The types of protection that we use to safeguard food against dust can also be used for fallout protection. The rays from fallout do not induce radioactivity in food, so if a well-closed package, a tin can, a glass container, or even a closed cardboard container is dusted off first to remove fallout and carefully opened, the food within it would be safe for consumption. Now as to fallout that comes from all-out nuclear attack on this country, there are more sophisticated procedures that can be tried. Dr. Lough mentioned some of those that are under consideration within the Executive Branch of the government at present.

Mr. Depew: Mr. Mulford: Do you think the approval of food additives should be a new drug type of approval; that is, each firm has to get approval for its additive even though it is the same as one already approved? Would this lead to duplication of research and wasted effort?

Mr. Mulford: No, I don't necessarily say it should be a new drug type situation. I just point out that this question, "what is the same," should be very carefully considered, particularly where the method of manufacture seems to play an important part, and where the first proponent submits all this information on the method of producing a product and other people do not have to.

Mr. Depew: The next question was addressed to Dr. Kern. I revise it and I hope Mr. McMurray may be able to answer it: Does industry believe new legislation is needed in the animal feed area? If so, what should be proposed?

Mr. McMurray: That's a rather broad question. New legislation is being proposed in this area. I can't speak for industry as to what proposals might be made. I think the question is too broad to answer.

Mr. Depew: Mr. Mulford: the speaker who talked about animal feed was worried because he had some trouble getting FDA to agree to let him put more chemicals into feed. He might be interested to know that many women would rather buy meat grown without all of his chemicals. The meat doesn't seem to have the flavor it used to

have, and I would like to know why we can't have it grown on plain feed again.

Mr. Mulford: There are some people who prefer the Virginia hams that are not subject to meat inspection and can't be shipped in interstate commerce. It is entirely possible to get this sort of thing for those that prefer them. Personally, I like to believe that our food laws and our inspection laws are there to provide safety for the people and also cleanliness which is, of course, an important factor and I think they do a very good job of it. If you want taste modifications, speak up. I am sure that somehow or other the meat producers will be able to satisfy the demand for that kind of product.

Mr. Depew: The next question I think I'll ask for Dr. Campbell's comments: Food is being packed in odd sizes now so it is hard for the customer to determine which product is the best buy, and it is being packed in boxes that are too big. Why do the manufacturers insist on doing this? Why don't they supply good food for a fair price instead of dressing up the packages so we can't tell what we are getting?

Dr. Campbell: Why do you ask me why the manufacturers do what they do? (Laughter)

Mr. Depew: I don't think there is anyone on the panel who would consider himself an expert in this particular field. I can say that I know that there is a need for mutual understanding in this field. Some of these convenience foods require that they be packaged in special sizes that are not of a standard net weight, and that there are also reasons for packaging a line of foods in a certain size package. If they were not all packaged in the same size, it would not only make it much more expensive for them to be sold and distributed, but it would make it hard for them to be displayed in the retailer's store.

Mr. Dierson, Counsel for the CMA, is in the audience. Would you like to comment any further on that question?

Mr. Dierson: If the assumption is clear that the package is deceptive, then of course it is subject to law and the violation can readily be reached, prohibited and punished. But suppose there is some doubt about the reason for the size of the package, which is subject to explanation. If such explanation by the manufacturer is persuasive, then again it seems to me the answer is clear. Furthermore, no manufacturer can long escape either the penalty of the law for violation or the penalty of defying the public intelligence by putting up a package which offends in this respect. In a technical or borderline

case a package, let us say, loses some of its bulk and gives the appearance of being slack-filled for such reasons as the shaking down of a cereal in transit or loss of moisture due to climate. This I think is a clear problem of loss of bulk for reasons beyond the manufacturer's control and notwithstanding his use of the best packaging practices. The public should make allowance for this, however, within appropriate physical tolerances.

Dr. Campbell: May I ask the manufacturers something on this? I mean is there a real objection to establishing standards of fill for containers?

Mr. Dierson: There is, Dr. Campbell, a general standard of fill of container in the sense that any headspace must not exceed a tolerance that is reasonable in relation to the nature of that product. Factors relevant to an appropriate tolerance include such product characteristics as changeable density, tendencies to absorb or to lose moisture, expansion or contraction with changes in temperature, etc. Accordingly, fill of container may have to vary with a great number of products. However, this general standard of a rule of reasonable fill has long and effectively been administered by the various state weights and measures officials and by the United States Food and Drug Administration. If a grocery manufacturer packs his product in a manner which offends the requirement of a reasonably full package, he finds himself exposed to prosecution for violating existing statutes which prohibit and penalize deceptively filled packages. The foregoing comment does not relate to the different question of a reasonable variation in weight from that declared upon the label.

Dr. Oser: May I add a word to that?

Mr. Depew: Yes.

Dr. Oser: I'm not defending any practice of the manufacturer, but an explanation of one reason for the odd weights, is the fact that there are cases where the manufacturer has a line of products, such as breakfast cereals or spices, where the same size container is used for practical reasons and for display reasons, the density of the various products that go into these packages necessitate odd weights. I say this without defending it, but this is a practical matter. This is also true for liquid products which are filled to a certain level but which vary in density.

Mr. Depew: Thank you.

A question for Mr. Kirk: Does the FDA intend to publish any list of materials deemed safe for use in the construction of process equipment and handling systems for food products—particularly liquid food products? Will such a compilation, if it is published, be of the blanket petition Food Additive Order type, or a list of materials generally recognized as safe?

Mr. Kirk: We have before us a number of petitions for regulations dealing with specific machinery items, and we will have to deal with those in different ways. Of course, there may be some items on those lists which are readily determined to be generally recognized as safe. Others may fall in what the inquirer calls a blanket sort of petition, and then there could be specific items. Since we're on the subject, I might mention that the fact that there are no regulations does not give any free ride. We have a number of extensions of the effective date for machinery items and if a food additive is getting into the food, where there is no regulation and there is no extension, that food is automatically illegal today.

Mr. Depew: Mr. Roe: Section 403 of the Food, Drug, and Cosmetic Act states that a food shall be deemed to be misbranded if in package form unless it bears a label containing,

> (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count: Provided that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

Will you please define what is meant by "reasonable variation" as it applies to weight and as it applies to liquid volume? If this variation is predicated upon a statistical basis, are copies of the method used available?

Mr. Roe: I think that's pretty well covered in the general regulation issued on that section of the law which does attempt to interpret the provision of the law for allowing certain reasonable variations. It is contemplated in the case of weight, for instance, that the average weight of a lot of goods will be that declared, that the variations above and below will average out to the proper weight, but the standard variations, either above or below, should not be large. Now we haven't set up a listing to indicate specifically what variations would be considered reasonable. I think that differs with the different types of commodities, the different size packages. This is simply a matter of trying to allow for a reasonable variation. Not every package in the carload is going to be exactly the weight declared, but the

law contemplates that the weight be just as close as reasonably can be done and it does indicate that we would expect as many packages to be above weight as below weight, if a reasonable attempt were made to comply.

Mr. Depew: Mr. Kirk, on the food additive petitions, FDA has 90 days after filing of the petition in which to act on the petition, and they may take an additional 90 days if desired. However, with regard to food standards, no action is required by the FDA, and frequently a petition to amend the standards sits without any action for a year or two.

Would the FDA initiate or support a move to legislate a reasonable time limit for action? Can the FDA legally establish time limits for action by means of procedural regulations? If they can, are they willing to? What other steps might be taken to speed up amendments to food standards?

Mr. Kirk: There's a lot to that. First, let me say that in my opinion, you do not get anything done any faster by having a regulation which says do it in 90 days. I think the answer to the problem here, and I readily admit that there is a problem in this food standards field, is to have us do the job faster not because we are told by a statute to do it in a certain number of days, but because it is a job which should be done and should be done promptly. We happen to be short of personnel in our Food Standards Office right now, and we are trying to rectify this. As I say, I don't think the answer is "let's pass a law." The answer is "let's get some people and do the job" which we too want done just as you people do.

Mr. Depew: Another question: There appears to be a great deal of confusion concerning regulations covering components of paper and paperboard used for food packaging. Please state what is being done to promulgate a blanket petition, and how can individual component manufacturers cooperate in the promulgation of a sound, all-inclusive regulation?

Mr. Kirk: Well, here again, as in the machinery field, we do have proposals for regulations. The American Paperboard Association and the Pulp and Paper Association have been working very closely with our people in this matter for a very substantial amount of time. Of course, we do have many extension items under the authority of this year's law, and I do expect that we will have a real, I guess the term is "blanket", everybody wants to call it blanket,

although I don't really believe it is, blanket regulation which will cover many facets of this paper operation. There are, of course, already a number of individual items which have gone through the petition route and have come out with regulations for use in making paper and paperboard, and I expect that we will continue to have individual regulations where the facts warrant.

Mr. Depew: Mr. Roe: How does one assure himself that fill of container is satisfactory for such items as loose-pack candies, cookies, etc., in: (a) a rigid box? (b) a flexible bag? In other words, are there any official or unofficial standards or guides for determining the proper size for the package, or for determining the per cent of fill?

Mr. Roe: We haven't issued any fill of containers standards for packages of that type. It is much more difficult for the Food and Drug Administration to evaluate the package than it is for the manufacturer to insure that he has a well-filled package. You are in position, of course, to determine how much you can put in the package without damaging the product and ascertain just what the conditions of holding are. We have difficulty sometimes in evaluating what the shake-down may be and so forth. But I think it is obvious that we do encounter from time to time packages that are not well-filled. However, from the manufacturers' standpoint he has no real problem if he takes the trouble to determine and to experiment a little bit how he can pack the material and just what the conditions are that he has to have in the way of a package to protect the product.

Mr. Depew: I have a couple more questions for you: There are standards of identity for jellies and preserves which regulate the quantities of fruit or juice to be used. These fruits or juices may be of a blend of varieties or lots or suppliers—in fact, they are often made of blends to achieve a particular flavor characteristic. Some manufacturers are now adding back fruit essences which were originally captured during the processing of fruits or juices. Is it necessary that the essences so used be used in conjunction with the specific lot of fruit from which they were obtained?

Mr. Roe: It is my recollection that the standards for preserves and jams call for the use of fruit, and I don't believe they make any provision for add-back of essences. However, if essences are trapped in the concentration of the jam and the juice and added back to the same lots, I think we would consider that it is part of the fruit used, but there may be some problems and some difficulty if essences from

other sources are used in such a product without specific recognition for it.

Mr. Depew: In the preparation of fruit juice for jellies, a cartridge-type filter is used. These cartridges consist of a core and a filetering media. These cartridges are disposable, being used a maximum of 8 hours.

(a) Is jute a satisfactory filter media?

(b) Is phenolic resin a satisfactory core material?

(c) Is tin-coated steel a satisfactory core material?

Mr. Roe: Well, I don't think I can answer those questions offhand. I think that's one that I ought to consider with some of my technical people. (Later, Mr. Roe supplied the following answers:)

(a) Yes, for this usage we are of the opinion that jute would be GRAS. However, the use of adjuvants in the fabrication of the filter would require a regulation under the Food Additives Amendment unless they were GRAS or prior sanctioned.

(b) Phenolic resins may perform satisfactorily as core materials but we do not regard this usage as GRAS and we are unaware of any prior sanction for it. Hence, a food additive petition is in order.

(c) Yes, for this usage we are of the opinion that tin-coated steel would be considered GRAS.

Mr. Depew: Mr. Goodrich: Since the Food Law Institute meeting of one year ago have there been any developments in continuing guaranties procedures?

Mr. Goodrich: None, except the new form of guaranty under the Federal Hazardous Substances Labeling Act.

Mr. Depew: Mr. Kirk: In view of the California court decision regarding mineral oil in confections, what is the current status of the use of mineral oil specifically in: (a) molding starch? (b) as a dust preventative in dry mixes?

Mr. Kirk: First, I don't recall any California or any recent decision involving mineral oil in confectionery. I think perhaps the inquirer may be referring to the artificial sweetener in confectionery matter. Be that as it may, mineral oil is still a food additive for the uses which you mentioned and if the molding starch and the other are intended for use so that the mineral oil will ultimately get into confectionery, of course, right now that would be barred under the provisions of Section 402(d), which deals specifically with nonnutritive substances in confectionery.

Mr. Depew: Dr. Campbell: A recent review of peanut butter packed in glass containers indicated some to be as low as 82 per cent fill. Is this satisfactory in your opinion?

Dr. Campbell: Well, I don't have any experience in that particular field. This goes back to this whole question of fill and what is reasonable fill. And we had one answer. Reasonable fill is what ultimately the court say is reasonable fill, but, as you know, the Food and Drug Administration has been involved in many cases, with not always happy results in these matters. This is an area in which, I think, we could have very fruitful discussions with the various parties concerned.

Mr. Depew: Thank you.

Mr. Roe: In the press there have been articles regarding the development of toxic substances in frying fats on continued heating. Is there any basis for this concern, and what should a deep-fat fryer do in the way of quality or process control?

Mr. Roe: Over a period of some years, there have been reports in the scientific literature that certain fats and oils may undergo some chemical change on prolonged or high heating, or abusive handling. Some reports have suggested that these changes result in some changes in nutritive values. There were even reports of the development of toxic substances and some suggestion that perhaps this change in fats and oils might have some relationship to certain diseases of humans. About five years ago, in the Bureau of Biological and Physical Sciences, we undertook some research studies in our Divisions of Food and Nutrition to determine just what the facts might be. We subjected various oils and fats to conditions of heat and prolonged heating in the laboratory, and we found that there are changes in the nature of polymerization. Our Division of Nutrition conducted feeding tests and found that some toxic substances did appear. In the meantime, the chick edema situation came up and other questions with fats and oils that indicate that there are some problems here. I would say, however, that from the information that we have developed and what we know from the literature, there is no particular concern with respect to the usual cooking fats and oils as used in the home in frying and in deep-fat frying, but there may be problems on abusive use, high temperature, or prolonged uses. We're still studying this problem. It involves some very interesting and very complex and very challenging scientific problems to identify these toxic substances

and to elucidate just what they mean. There is basis for further research and further study of the problem.

Mr. Depew: Mr. Roe: In a press release from HEW several months ago, it was indicated that in checking weights of spices consideration is given to loss of weight through evaporation. Specifically, what are the allowances, and how are they determined?

Mr. Roe: I have no specific numerical allowances that we can list for you. But this problem, the matter of possible evaporation and change in weight of products due to evaporation or loss of moisture is something that has to be considered every time we check weights on such products as flour, cereals, and spices. They may have dried out so that the apparent short weight may be due to loss of moisture. Well, what we do, of course, is include moisture determinations in our examination and reference back to some standards that we have in some of these products. We have in the past made many experimental shipments of various kinds of foods in various kinds of packaging to determine what changes in weight may occur under certain temperature and humidity conditions. Sometimes weights increase and sometimes they decrease. Here again, it is a matter of examining all of the facts and determining the significance of the findings in terms of the weight that should be there at the time of shipment.

Mr. Depew: A question for Mr. Clark: Assuming that an article normally used in the household is not a chemical-like substance but is in the nature of finished goods, that is, a child's toy, hair clip, etc., would such an article be subject to the law if it were composed of substances which might in and of themselves be toxics, irritants, or flammables?

Mr. Clark: Well, basically, I believe that is the same as an earlier question. The determination as to whether a product falls under the law and the labeling that would be required for it is based on a determination of the properties of the finished product. If such an article contained an ingredient that was toxic or irritant, that would not necessarily bring the final product under the Act.

Mr. Depew: Would the law apply to such substances if sold in bulk without containers? If so, how and under what provisions in the Act?

Mr. Clark: Is this a part of the same question?

Mr. Depew: Yes.

Mr. Clark: The term "bulk", of course, would need definition. To be subject to the Federal Hazardous Substances Labeling Act a product must be in a container "intended or suitable for household use."

Mr. Depew: Another question in the field: Do the exemptions afforded by Section 191.63 (for papers, matches, etc.) imply that all such finished articles which might be flammable and sold in containers or packages must be specifically exempted from the law?

Mr. Clark: Well, if a product meets the definition for flammable solids and it was in a container intended or suitable for household use, and if it could be anticipated that through reasonably foreseeable handling or use, an injury might result, then it would require labeling under the law unless it were exempted. It might be possible under the same consideration that exempted paper and paper products, to exempt other types of solid materials if the facts were presented which indicated that even though they met the definition for hazardous substances, they did not present a practical hazard.

Mr. Depew: Mr. Kirk: Is it true that FDA will no longer issue advisory opinions about packaging or processing materials components contended to be exempt from the Food Additives Amendment by reason of reasonably demonstrable "no migration" to food?

Mr. Kirk: The situation has not changed since last year's meeting. At that time, we discussed the very situation where we had been receiving reports of extraction studies which did not show any migration to the food. We wrote letters stating that we agreed that these items were not food additives. After many of these had issued, we found they were being used as sales promotion pieces, often to the detriment of other firms who had the same items, and had properly made up their minds without consulting us that the Food Additives Amendment did not involve their items. As a result, we concluded that we could no longer issue that kind of letter. Additionally, there were instances where small amounts of migratory substances were, in our opinion, properly classed as food additives. As a result of our reconsideration of the situation, we stated that we would, if requested, review data submitted to us and if this represented the right kind of work, I say right, as recommended by Mr. Ramsey's article, for example, and showed no migration, we would issue a letter which, unfortunately, would not be a letter suitable for advertising. Essentially, the letter would say: "You made your mind up. You have a perfect right to do so and even though you didn't give us any reason

to say that you're wrong, we still have no facts of our own on which to agree."

The other alternative is that if you want a "letter", the way to get it is to submit a petition for a Food Additive Regulation. If we can find that the product and the use involved are safe, then we can issue a regulation which will be there for all to see and will apply to everyone who has the same product for the same use.

Mr. Depew: Another question: Will FDA continue to issue such opinions as regards believed "prior sanctioned" or "GRAS" status of packaging or processing materials components?

Mr. Kirk: Oh, yes. If someone asks if a product has a prior sanction we will tell him so. Similarly, if he says here is a usage which we believe is GRAS (generally recognized as safe), if we agree, we will say so.

Mr. Depew: Mr. Goodrich: If a "non-migrant" must be cleared through the petition-regulation route, does it thereby become a "food additive"? If so, must it not be conceded that the terms "food additive" and "food" are in no sense equitable per se, and that the manufacture of "food additives" of this nature does not form a basis for FDA's use of its plant inspection and similar powers as to such manufacturers?

Mr. Goodrich: This is the third year now for this question. We have to understand that a food additive is not necessarily something added to food. If we understand the definition, we solve a lot of our troubles. A food additive is any substance the intended use of which results, or may reasonably be expected to result, in its becoming a component of food, or otherwise affecting the characteristic of food. Now, unless it's known from the behavior of this substance that it will not migrate, there is a reasonable expectation that it might, if it is going to come into contact with food. Therefore, by definition, it is a food additive. A food additive, as explained by the legislative history of the Food Additive Amendment, is subject to the food provisions. We're not yet interested in requiring that a tin can be labeled with its ingredients, however.

Mr. Depew: Mr. McMurray, this questioner says: It was clear to me that the speaker who talked about the Kefauver bill was against it, (Laughter) but I would like to know whether he is against any drug legislation.

Mr. McMurray: Well, Senator, (Laughter) no, definitely, not against any drug legislation. Certainly, we recognize that we need

regulation in the drug industry. Those of us who feel that our particular corporation runs in a fashion which is beyond reproach, realize that we and others need to have the confidence of the people who buy the drugs. This confidence is engendered by legislation which brings regulation and if it is fairly administered, we not only are not against it, but we welcome it. I think good partnership between the Food and Drug Administration and our industry has brought us to where we are today. I think living under the present drug laws has made us a very strong industry with a lot of confidence on the part of the people who buy drugs. So, no, we're not against it.

I think what we are against, and I want to make this point, we're not against all of the features of the Kefauver Bill and I think when I spoke yesterday, I didn't editorialize on the bill, but merely pointed out the parts of it. Some of it's good. Some of it will not be opposed by the industry. We are, I think, opposed to any unfair legislation whether it regulates us or whether it regulates anybody else. Fair regulation we welcome.

Mr. Depew: Mr. Kirk, the Food Additives Amendment provides such petition shall contain "(B) a statement of the conditions of the proposed use of such additive, . . ." Some petitions and the resultant regulations are very specific, that is "EDTA in pecan pie fillings," others use very broad terms such as "for use in bakery products," "for use in or with shortening," etc. Is the specificity of the petition and eventual food additive order at the discretion of the petitioner?

Mr. Kirk: Well, what is in the petition is, of course, at the discretion of the petitioner. He should keep in mind, however, that in order to get a regulation, he must show what he wants, he must show what the physical or technical effect of the additive is, and he must show that he is using no more of the additive than is necessary to achieve that effect. Therefore, if someone comes in with a petition covering a wide range of substances, he must justify across the board. On the other hand, if a petitioner is really only interested in one specific usage at the moment, as, for example, EDTA in pecan pies, all he has to do is limit his petition to that and assuming that he satisfies our technical people as to usage, safety, identity and methodology, he gets that specific regulation. He can, however, come in later and say: "I would like to have this in strawberry sundaes and we would have to consider that, too."

Mr. Depew: That has somewhat anticipated the next question: If a food additive has been approved for a number of specific uses,

does each additional use proposed require a separate petition with the concomitant paper work, processing, etc., by the petitioner and the FDA?

Mr. Kirk: Well, the new petition could cover a number of uses. Similarly, if he has submitted all of his toxicological data in the first petition, certainly he doesn't have to have it all duplicated so that we can have it available in the second petition jacket. We do know where we filed the first one.

Mr. Depew: Another one for you: The law provides upon request of the secretary, the petitioner shall furnish "a full description of the methods used in, and the facilities and controls used for, the production of such additive." If a petitioner has obtained approval for a food additive in which he has been required to furnish the information required under (3) above, is he obligated to notify the FDA if he finds he can make the product by an improved process?

Mr. Kirk: Well, I think I heard some discussion of that yesterday. Actually, the answer should not be "yes." This recalls Mr. Mulford's discussion of yesterday. We ask, in many cases, for details of manufacture, but I believe we should evaluate all of that information we get and decide which of this information is essential to the identity and safety of the particular product involved.

Now, it is conceivable that you might want to know what specific oils were used and then after you find out, decide that it didn't make any difference whether it's corn oil, palm oil or what kind of oil, in which case the regulation obviously shouldn't tie it down. But if there is something in the manufacturing process which should be specified, I believe that should be in the regulation. Then, if the manufacturer wants to change that particular facet of his proposal, he would have to come to us before the change would be legal. Similarly, if anyone else wanted to make the product, he would have to stay within the framework of that particular manufacturing process as far as it is spelled out in the regulations.

Mr. Depew: Another one: Should not other manufacturers be required to prove they produce the same product by equivalent means and facilities and from equivalent raw materials?

Mr. Kirk: Essentially, I think I covered that. In other words, they should follow the regulation and come out with the product, meeting each step in the regulation.

Mr. Depew: Another one: If a company has been required to give precise details of manufacturing and raw materials used to obtain

approval of a food additive, is it not incumbent upon the FDA to preclude the manufacturer or other manufacturers from marketing a similar, but not identical, product under the said Food Additive Order?

Mr. Kirk: The Food Additive Order contains certain specifications which go to the identity of the particular article. Now, obviously, if the second product involved, or the second manufacturer's product is not identical with the one specified, then that needs a new regulation. We have a situation where we provided a regulation for a distilled product. Someone comes to us and says: "We have the same product which is not distilled and we think it's the same." We say: "Fine, give us the data showing the safety of it and we will be glad to issue a regulation."

Mr. Depew: Mr. Roe: What effect will it have on the public confidence in the 1958 Food Additives Amendment if it should become known that an ingredient has been generally recognized as safe by the FDA without soliciting the opinion of any other "experts" especially in the case where the FDA ruling is based on data which may or may not describe the ingredient now being marketed?

Mr. Roe: Well, I can't say right off-hand how we would just, off-the-cuff, on our own, issue a declaration that an item was generally recognized as safe unless it's so generally recognized that it is shown by reports and the literature and so on that there is no question about it. Otherwise, we would have consulted with other experts. But, assuming, however, that an article has been classed as generally recognized as safe, and we find that a mistake has been made, new information comes to light or information that we had overlooked before that shows it isn't generally recognized as safe, I think there would be no problem in promptly rescinding its status and doing whatever needed to be done to give it the status that it deserves under the new information.

Mr. Depew: Another question: Should ingredients approved under a prior sanction or GRAS list enjoy any less stringent labeling requirements than food additives?

Mr. Roe: Food additives would have been the subject of a Food Additive Regulation, which may contain special labeling requirements, whereas, the GRAS product, not subject to such a regulation, may not have those requirements, although the terms of the announcement of it as GRAS might cover that. But at any rate, whether it was a food additive under the Food Additive Regulation or a product generally recognized as safe, it would be subject to all of the other

general labeling requirements of the law. The only difference would be if the Food Additive Regulation makes special labeling requirements for that additive in addition to the general requirements.

Mr. Depew: Dr. Banes, this questioner says: You stated that many poisonous products would escape the requirements for precautionary labeling if the limiting does for toxic substances were reduced from 5 gm. per kg. to 1 or 2 gm. per kg. Would you give a few examples of such products?

Dr. Banes: The statement was made, I believe, in Mr. Harvey's talk and was made on the assurance of our Division of Pharmacology. Among the substances which come into that category would be certain of the common solvents, including methyl ethyl ketone and benzene; some chlorinated solvents (trichlorethylene, methylene chloride), some of the harsher detergents, I think were mentioned by Dr. Ligon yesterday, inks from stamp pads, dyes and products containing dyes which might be toxic at the higher level, the 5 gm. level, but not at the lower. Dr. Adams, perhaps, may be able to add some other examples.

Dr. Adams: As a sideline comment, I think it was well-covered. Sure, we could bring out others, but the general field is there.

Mr. Depew: Thank you.

Mr. Kirk: Certain Food Additive Orders give a list of optional ingredients which may be used for specific purposes plus a performance for the finished product used for this purpose. For example, paragraph 121.2514 on resinous and polymeric coatings list a number of ingredients such as (1) drying oils, (2) rosin and rosin derivatives, (3) polybasic acids, (4) monobasic acids, (5) polyhydric alcohols, and (6) catalysts which may be used in coatings for can linings if "the coatings are formulated from optional substances that may include" and optional substance listed and if the coatings in the finished form shall pass certain extraction tests also described and made a part of the regulation.

The question is, if a substance not listed which may have been overlooked or developed subsequent to the order is used to produce a coating which passes the extraction tests, is it safe for use in containers intended for use with foods and may such coatings be used under this regulation?

Mr. Kirk: Whether it's safe or not, I don't know. But it is not legal to use it. The two parts of the regulation are additive. In other words, the items which are listed are the ones which may be used and

the extraction test is added on top of that. In the illustration here, the "overlooked" item perhaps could be the subject of a further regulation based on a further petition for an amendment to the regulation if the facts warranted it.

Mr. Depew: Dr. Campbell: Do you think that the FDA is responsive enough to the consumer interest? If not, why not, and how could matters be improved?

Dr. Campbell: Well, I have worked quite closely and have a great deal of admiration for what the FDA has been trying to do over the many years. As you know, there has been development and Miss Carla Williams, who is now here, has Consumer Consultants in different parts of the country, in order to try and get closer contact with consumer opinion on matters of concern to them, and also, through regular annual conferences to get an expression of opinion from the people who are actually involved in buying the foods that the FDA is protecting. And I think this is a very positive development that we welcome very much.

Mr. Depew: Mr. Clark: It was mentioned, I think by Dr. Ligon that FDA may issue an order exempting certain substances from the category of toxic substances, such as soaps, washing powders and thick viscous adhesives. Is it intended also to exempt certain products by order of the Commissioner by virtue of the size of the containers, the type of materials of which they are composed, or the types of closure?

Mr. Clark: Yes, the statute very cleary contemplates the exemption of products which meet the technical definition of a hazardous substance but because of the physical characteristics, the type and size of the container, the type of closure, or any other good and sufficient reason it can be demonstrated that the public health and safety does not need the protection afforded by the complete labeling. For this purpose we have developed the informal petition process mentioned by Mr. Harvey yesterday. Anyone who has a package of a product that for some reason is actually not hazardous, we will be glad to entertain a petition for exemption of that product even though it meets the technical definition of a hazardous substance.

Mr. Depew: Mr. McMurray, the next question is a brief one: Why are drug prices so high?

Mr. McMurray: This is one of those questions, like when did you stop beating your wife? Well, let me say that drug prices are set

as they are to accomplish the purpose of the corporation or the company which produces the drug, which maintains a plant, equipment, pays highly trained, highly skilled personnel, pours much money into research, pays taxes, provides fringe benefits, etc., grants in aid, all of these things plus what they consider to be a fair return to their shareholders. The question, I think, is not answerable but why are drug prices as they are, they are to return the fair profit on the product sold to companies which are still operating a free enterprise system.

Dr. Campbell: May I ask something on that? May I ask a follow-up on this?

Mr. Depew: Yes.

Dr. Campbell: I was rather interested in the words that Mr. McMurray used. He said drug prices are set. Now, of course, in a free market mechanism, this creates quite a problem and it may be that you had in mind the area of resale price maintenance in connection with drug prices, or, on the other, that the drug industry is powerful enough to be able to "overcome the free market mechanism", I'm not too sure which point you're making here?

Mr. McMurray: May I disabuse you rapidly. (Laughter) The word . . .

Dr. Campbell: With great respect, Mr. McMurray.

Mr. McMurray: Yes, and I, too, Doctor. The word "set" was an unfortunate word in this . . . (Laughter) . . . but I'll accept that. When a price is determined, within a corporate entity, it is done with an eye toward the conditions that exist within that corporate entity, not within the industry as a whole.

Mr. Depew: Dr. Zapp, this questioner says: I am surprised that the companies that make hazardous household substances have complained about the regulations FDA has put out. The law was passed because all of the voluntary measures Dr. Zapp talked about still failed to take care of the products that were harming people. Do the manufacturers think FDA should pass regulations that don't require them to make any changes?

Dr. Zapp: Well, here's another question which, in effect, states a conclusion. The law was passed . . . would you repeat that one sentence, the law was passed because?

(Mr. Depew repeats the question)

Dr. Zapp: All right. That's the conclusion. I do not agree with that conclusion. That isn't the reason the law was passed as I see it. Perhaps the overwhelming reason that the law was sought by industry and government and consumers, was to get some degree of uniformity into labeling situations which had grown up and had, therefore, become somewhat nonuniform with respect to different parts of the country. Certain states, for example, had passed their own labeling acts and the time was ripe, I think, that uniform standards be instituted for the country as a whole. This isn't because, as I see it, there was any failure in the kind of labeling that we've had before, but rather an attempt to bring uniformity into a situation where there was an opportunity for diversity to exist and where such diversity, I think, would have been very inefficient and somewhat chaotic.

Mr. Depew: Dr. Banes: Mr. Harvey has defended the refusal to allow greater latitude in the choice of toxicity tests on the ground that the FDA methods were "precise and reproducible." Are they any more so than other methods and, if so, has this evidence been published? Also, is reproducibility to be preferred to accuracy or reliability as an index to possible human hazard?

Dr. Banes: The statement that the tests provided in the regulations are reproducible and precise and therefore are to be preferred to others, I think, doesn't take into consideration what is implied—that these tests also must be accurate and reliable as well as relevant. We keep insisting upon reproducibility and precision for the reasons discussed by Dr. Zapp in his discussion yesterday. The very nature of animal testing makes such tests variable from laboratory to laboratory. We would not insist upon the inclusion of a test in the regulations unless we were fully confident of the reliability and accuracy of that test. So reliability and accuracy are the prime factors to be considered and not precision and reproducibility. As to whether there are other more precise and reproducible tests in the literature, I don't know. But we do insist upon accuracy and reliability. Now, we also feel that these tests that are in the regulations are also reproducible, which is also a desideratum in analytical procedures.

Let me say though, in answer to an implied question there, "Are there any other tests that are more accurate and reliable than those we have set forth in the regulation?," I don't know. If there were any more reliable and accurate tests, we would be only too happy to include them in the regulations. Regulations are not unalterable. If a better test presents itself, then we will accept it.

Now, as to another question that Mr. Zapp discussed yesterday, that perhaps he would like to discuss further here. Suppose that there are a variety or series of reliable tests that serve the same purpose. Wouldn't it be possible to permit other laboratories to use them? The answer is that any laboratory can use any test that it deems reliable to show that a product complies with the law.

On the other hand, to enforce a law it's necessary to have a specific test to bring into court in order to say the data show that it does comply, or it does not comply. Now, where a product clearly complies, any reliable method will be suitable, and, in fact, I'm sure the Food and Drug Administration would have difficulty making its case in court if it were to say that its method shows a violation, whereas another method which scientists say is equally reliable shows it does not violate the law. It's only where there is a question in the gray area that there is a valid problem as to what method shall be accepted.

Now, if there were a possibility of alternatives, that possibility of alternatives would lead to all kinds of litigation. If we may take the example of the U. S. Pharmacopoeia, that compendium never provides an alternative for an official procedure. For every assay there is only one procedure provided officially and the purpose for that is to cut down litigation about whether this method or that is the best. I don't see how we could possibly enforce a law where we say any reliable method might be used. The time of the court would be taken up almost exclusively in arguments about which method is the better.

Mr. Depew: Do you wish to comment on that, Dr. Zapp?

Dr. Zapp: I could add a little. I think that in the vast majority of cases, substances that are subjected to tests will fall clearly to one side or the other of any line which may be drawn. Then there's no argument about the classification of the substance. When we come to the difficult cases, we may have to use a variety of methods to reach a valid decision. What the regulations have done is to establish a technical rule which says you do the test in a particular way, and you come up with a number. If the number is equal to or greater than a given number, then you must use cautionary labeling. This kind of rule is quite clear and simple. I think that the real argument comes, and can legitimately come, over the meaning of the arbitrary number in relation to the human response, as contrasted with the animal response. I agree that the methods that have been used by Dr. Draize, for example, are good and I'm sure they give reproducible results in his hands. I also feel that the methods used in my laboratory are good

and give us reproducible results. But if Dr. Draize and I were to use the same method, we would not necessarily get the same results. The difficulty is that animal tests involve both a factor of biological, variation, which is inescapable, and a factor of human judgment with respect to how even a prescribed test is to be carried out and interpreted. The operation of both of these factors could lead Dr. Draize and I to get different results using the same test substance and the same test method—either his method or my method. For example, the irritation response of rabbit and guinea pig skin to some classes of substances is affected by the humidity of the environment. Hence Dr. Draize and I could get different numerical scores for skin irritation if we tested under different conditions of humidity. And if we did differ, it would not be easy to say who carried out the test correctly. And humidity is only one of the variables present. Another important one would be human judgment as to the numerical score to be assigned to a given erythema. There are many others.

We must remember that the task before us is to estimate as best we can by any animal test the human response to a test substance. Hence a score of 5 in the Draize test for skin irritation is important only as it estimates whether the material produces irritation of human skin.

Actually, I see little point in establishing an official animal test for skin irritation potential because skin irritation tests can be carried out safely and easily on human volunteers, and the response of the latter should control in the event of litigation or a dispute over the interpretation of animal test results. For other categories, an official animal test may be the only feasible approach in the initial stage before human experience is available. But even here I feel that an animal test method should be made official only after trial in a number of referee laboratories with standard test substances and after a consensus is reached among competent investigators that the method is, in fact, the best available method at the moment. It follows also on ample precedent that official methods should be subject to periodic review and to revision when indicated.

Mr. Deprew: Yes, Dr. Oser?

Dr. Oser: From the toxicologist's standpoint, there is no essential difference, as I see it, between establishing the toxicity of a hazardous substance and establishing the toxicity of a potential food . . . additive.

Dr. Zapp: How do you reconcile the policy of the Food and Drug Administration in insisting upon specifying tests in the regulation for hazardous substances, and in supporting the general opinion of toxicologists against specifying tests for food additives? Can you answer that?

Mr. Goodrich: They are two different laws, which you know. First, in order to get a food additive petition effective, you have to come up with a methodology and obtain an advance approval. In the case of a hazardous substance, you do not. The burden is on us to go into court and prove before a court and a jury that this is a toxic substance, which is undefined, an irritant substance, which also is undefined, a corrosive substance which is undefined, or one that generates pressure. Now, Congress told us to establish standards for flammable solids and things of that kind, and we came up with methods of testing for irritants, corrosives and that type of thing. The only specific objections we got here were over such things as stocking the rabbits, and that you want to do your tests a little bit different than we wanted to do ours. But the sole alternative, if we do not have these methods, is to try out before some district court or some district court jury on the question of what is the right way to test a rabbit for skin irritation. This is not very productive work. I believe Ken Mulford will agree with me on that.

Dr. Oser: I would like to ask a question? Can you envision a situation where for some reason a product would not pass the test described in the regulation, but would pass another regarded as equivalent, and despite this difference the product would be considered by FDA to be nontoxic?

Mr. Goodrich: This all gets down to the obvious point that we're not going to try a seizure case or criminal case over something where there is a difference of this kind—the same result is obtained by two different methods. In this case that you're talking about, if we had a result shown on our method where you had an irritant and Dr. Zapp came up with human experience where the product was not an irritant, and could demonstrate that, then obviously we're not going to take the rabbits into court against his human beings as a practical matter. But we have to have a method that at least has some scientific support, or go to trial on what happened to the rabbits, what happened to the rats, and this, that and the other, and it just doesn't work out. I'm sure these scientific people would be the most disappointed of the crowd when we got all through trying out whether a method was a

good method, or a bad bethod, because lawyers can make this type technique look pretty awful if you don't understand that there is such a thing as a "normal abnormality." (Laughter).

Mr. Depew: Thank you, all. I think we have completed the answers to that question.

I have a very interesting question here for Dr. Adams: Could not the difficulty of dealing with the toxicity of the one and one-half to two and one-half million compounds now available to us be eased by using a gradient scale symbology? Thus: one skull and crossbones, two skulls and crossbones, (Laughter) up to five skulls and crossbones. The degree of toxicity shown on a gradient scale by the use of multiple skulls and crossbones instead of the single symbol. The nature of the danger could also be shown by pictographs representing the hazards as a nose for breathing, a fire for flammability, a bomb for explosion, a mouth for ingestion, etc.

Dr. Adams: My son, at the present time, is trying very hard to be an artist. He doesn't draw pirate ships, but he does draw submarines. I've never yet seen a pirate ship that flew five Jolly Rogers and I think that all of the ships running away from them would run just as fast from those that had one Jolly Roger as they did from five.

I think the second part of the suggestion has certain merit. The difficulty is that it would require that one label products with symbols that would be understood in all the various parts of the country. I think that one could go to parts of the eastern mountains of Kentucky and get an entirely different interpretation than they might in the New York area. So that I think unfortunately it would be impractical because I doubt that we could come up with a single symbol for each of these things that would be readily understandable.

Mr. Depew: Mr. Clark, would you like to comment on that?

Mr. Clark: Well, I might say that Congress, in passing the statute, didn't specify any visible symbols. They chose to select warning signal words. Our regulation recognizes the established skull and crossbones for some products. I agree with Dr. Adams that the use of other symbols might, in the future, coupled with an educational campaign be of some value. It might have real value to small children, who couldn't read but could recognize the picture of a flame or some other symbol.

Dr. Adams: Smokey, the Bear" is an excellent example of this.

Mr. Depew: A question for Mr. Clark: Section 191.7 of the regulations for the Federal Hazardous Substances Labeling Act specifies certain labeling for methyl alcohol and products containing it. Such required labeling does not include "flammable," which is recommended in the Labeling and Precautionary Information Manual. Why?

Mr. Clark: The labeling required in Section 191.7 is special labeling brought about by following the recommendations of the Medical Advisory Panel that methyl alcohol needed special and additional supplementary labeling statements, warning statements. This does not eliminate the need for any other warning statements which would be called for under the law. Substances which are flammable would also require that statement of hazard.

Mr. Depew: Another question Mr. Clark: We have a product that is registered with the Department of Agriculture under the Federal Insecticide, Fungicide and Rodenticide Act. The label gives other uses for the product. Must its labeling comply with the Federal Hazardous Substances Labeling Act?

Mr. Clark: No, the statute is very explicit in exempting from its requirements products that are subject to the Federal Insecticide, Fungicide and Rodenticide Act. So if it is an economic poison under that statute, then it is exempt from the requirements of the Federal Hazardous Substances Labeling Act.

Mr. Depew: Another question: If a firm has applied for a labeling exemption for a household hazardous substance, can they wait for a ruling on it before revising their labels?

Mr. Clark: No. There is no built-in machinery for putting into abeyance compliance with the law awaiting a ruling on an exemption.

Mr. Depew: Mr. McMurray, I have another question here for you which you may feel you have already answered. If you do, please say so.

Why are the profits of the drug manufacturers so high? (Laughter)

Mr. McMurray: I don't feel that they are. I don't feel that I answered that question either. I think that it has been put in the record of the Kefauver hearings and will be put in again commencing about December 7th. I think that a positive showing of reasonableness as far as profits in the drug industry is concerned will be put forth. I think the average of profits in the drug industry is about

10 per cent of sales, which seems to me, not to be an unconscionable profit for the high risk business what we're in.

Mr. Depew: Mr. Clark, if products are labeled "For Industrial Use Only" can the labeling required by the Hazardous Substances Labeling Act and its regulations be omitted?

Mr. Clark: There isn't any yes or no answer to that. What we did say in the regulations was that an industrial product, if it was used for industrial uses and did not enter the home, did not come under the provisions of the Act. The mere labeling of a product for industrial use only would not in itself exempt it from the statute. It would depend upon the distribution pattern.

Mr. Depew: I have a number of questions for Mr. Kirk:

A substantial number of the food additive regulations contain labeling requirements for the additives and any pre-mixes. Why do they not additionally specify what label declaration is required when the additive is employed in foods ready for consumption?

Mr. Kirk: Very deliberately, the Food Additive Regulation labeling requirements are designed only to include those items which are necessary to insure the safe and proper use of the additive. The other provisions of the law which deal with required labeling still apply and we saw no reason to repeat them in the Food Additive Regulation.

Mr. Depew: I have not seen any recent lists of extensions of the effective date of the Food Additives Amendment in the Federal Register. Does this mean that FDA has completed its evaluation of all requests for extension?

Mr. Kirk: Just about. We have a few pending requests which can't really be handled until we get some more information, but we're just about up to date on that now, although, of course, we may get some more requests for extensions tomorrow. That is possible.

Mr. Depew: I manufacture a food additive which was covered by an extension last year. This was obtained by another firm. I have just discovered that there is no further extension. Can I, at this late date, petition for an extension without first contacting the firm that requested the extension last year?

Mr. Kirk: Yes, you may request the further extension yourself, but it is, of course, necessary that you supply us with the necessary information as spelled out in the regulation we issued last April.

Mr. Depew: All of the current extensions of the effective date of the Food Additives Amendment which go beyond January 1, 1962 have specified dates for submitting progress reports which will be required at six month intervals. Is there a form for submitting these progress reports?

Mr. Kirk: No.

Mr. Depew: Suppose the time for submitting a report arrives and I have nothing definitive to report?

Mr. Kirk: Just tell us what you're doing and why there is nothing to report.

Mr. Depew: What happens if FDA does not receive a progress report as required?

Mr. Kirk: We'll have no choice but to cancel the extension. That is, the progress report is a condition.

Mr. Depew: I think that should be very clear.

I received recently from the Food and Drug Administration, a set of regulations for food additives and this included several extension lists. Some of these lists are no longer applicable but it seemed to me that their distribution by FDA may cause confusion. Do you agree?

Mr. Kirk: Yes, we agree. Those are the extensions which were to expire last March 6th. Now, of course, the current extensions are under another section of the regulations. What we're proposing to do is to cull out those former extensions and see to it that they are not republished in the U. S. Code of Federal Regulations.

Mr. Depew: Dr. Adams: Could you tell us a bit more about your Poison Control Centers? Is there usually a physician on duty round the clock to give immediate information on the toxicity of given chemicals and the antidotes thereto? I have had poor experience with the local one and hope that this is not typical.

Dr. Adams: The function of the Poison Control Centers is an entirely local situation. They vary from having full-time physician coverage round the clock to entirely different methods of handling it. I cannot speak for any specific one because each program has developed according the funds available in the community, the interest in the community, and the other things that have to be taken into account. I would hope that some time central information offices would be available that would offset some of the difficulties that do occur.

Mr. Depew: Mr. Kirk, again: The Food Additives Amendment does not contain any provision for referring questions to an advisory committee as does the Pesticide Amendment. Yet I understand that FDA has established such a committee to consider the question of using quinine in beverages. How does this happen?

Mr. Kirk: This is not an advisory committee in the sense that we have them under the Pesticide Chemicals Amendment. This is merely an illustration that the Commissioner, whenever he feels the need, has the right to go out to competent scientists and get their opinions to guide him in making such decisions as are necessary. It is not a formal committee, but it is a group set up to advise the Commissioner.

Mr. Depew: It seems that FDA has stopped issuing additions to the Generally Recognized As Safe List. Has FDA decided that there are no more substances in this category?

Mr. Kirk: No, actually we have, in correspondence, agreed with some people that additional items are GRAS. However, our personnel that might be engaged in considering a further GRAS list at this time are so busy trying to get out regulations and deal with the petitions that are before us that we've just put this activity to one side for the moment.

Mr. Depew: There are several hundred flavoring additives for which the effective date of the statute has been extended to January 1st, 1963, with a progress report required on January 2nd, 1962. It has been stated that the progress report should be submitted by the person, or firm, whose original request resulted in the time extension. How may we determine the one whose responsibility it is to submit the progress report, so that we may check to be certain that it is done?

Mr. Kirk: Anyone may ask who requested the extension that's been published in the Federal Register and we will tell them.

Mr. Depew: If a regulation by FDA has been issued which indicates that there is no migration, by the current accepted analytical procedure, of an indirect food additive that would be covered by the Delaney Clause, but improvements in the analytical procedure should be developed which would detect an exceedingly small amount of migration what procedure would be followed by FDA?

Mr. Kirk: If you have a Delaney Clause carcinogen, which is subsequently found to become a part of the food, then, of course, it would conflict with the Delaney Clause and there would be no choice

but to rule it out, because you cannot have a regulation for such a substance.

Mr. Depew: What action in behalf of industry would be appropriate for the establishment of a procedure which would allow an original petitioner to comment on a regulation by FDA before it is published in the Federal Register?

Mr. Kirk: Usually, people who ask for regulations tell us what they ask for. They spell out why they want it and then at the end, state the way they think the regulation ought to be. Now, it is, of course, difficult to sit down and say: "Well, we have decided this is the way it is going to be and let's talk about it," because if you did that in every case, I don't think you'd ever get done.

Mr. Depew: Thank you.

This completes the questions which have been submitted to the panel. I think the answers have rounded up the information which was given earlier in our papers and that this panel deserves your heartiest applause—they've answered some very difficult and technical questions. I think you will agree. (Applause)

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