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Food Drug Cosmetic Law JOURNAL

1960 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc.— Concluding Papers Presented at Consumer Session and Questions and Answers at Panel Session on November 29

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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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About This Issue.—The concluding papers of the 1960 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc., are published in this issue of the JOURNAL. They include the papers presented at the consumer morning session on November 29 and the panel discussion of questions submitted to the conference that afternoon. The proceedings of the November 28 sessions of the conference were published in the December, 1960 issue of the JOURNAL.

At the FLI dinner on November 28 the Institute's Award for Distinguished Food Law Services to the American People was presented to the Food Protection Committee of the Food and Nutrition Board, National Academy of Sciences-National Research Council. Dr. William J. Darby of the Vanderbilt University School of Medicine accepted the award for the Food Protection Committee.

National Medal of Science.—On January 18 President Eisenhower issued an Executive Order prescribing the design of the National Medal of Science. The medal was established by the Act of August 25, 1959.

Each individual awarded the medal will receive a Presidential citation descriptive of the award. As required by the 1959 law, the President's action was based upon recommendations made to him by the National Science Foundation.

In any one calendar year, the medal may be awarded to not more than 20 individuals who in the judgment of the President are deserving of special recognition by reason of their outstanding contributions to knowledge in the physical, biological, mathematical or engineering sciences. The classes of persons eligible for the award are described in the order, which follows:

"Executive Order Providing for the Design and Award of the National Medal of Science

"By virtue of the authority vested me by the act of August 25, 1959, entitled 'An Act To Establish a National Medal of Science To Provide Recognition for Individuals Who Make Outstanding Contributions in the Physical, Biological, Mathematical, and Engineering Sciences' (73 Stat. 431), and as President of the United States, it is ordered as follows:

"Section 1. *Specifications of Medal.* Consonant with recommendations submitted by the National Science Foundation pursuant to the first section of the said act of August 25, 1959, the National Medal of Science established by that act, hereinafter referred to as the Medal, shall be of bronze, shall be of the design hereto attached, which is hereby made a part of this order, and shall have suitable accompanying appurtenances. Each medal shall be suitably inscribed. Each individual awarded the

Participants in the 1960 Joint National Conference of FDA-FLI are shown in the above photograph. In the front row, from left to right, are George P. Larrick, Carla S. Williams, John L. Harvey and Margaret Ives. In the back row are Richard Gordon, James Kittelton, William T. Brady, Franklin D. Clark, Wilson B. Rankin, Franklin M. Depew, Joseph D. Becker, Bernard L. Oser, Kenneth Kirk and Robert N. Johnson.

Medal shall also receive a citation, on parchment, descriptive of the award.

"Section 2. *Award of Medal.* (a) The President shall award the Medal on the basis of recommendations received by him in accordance with the provisions of this order to individuals who in his judgment are deserving of special recognition by reason of their outstanding contributions to knowledge in the physical, biological, mathematical, or engineering sciences.

"(b) In addition to the criterion stated in section 2(a) of this order, the following shall govern the award of the Medal:

"(1) Not more than twenty individuals may be awarded the Medal in any one calendar year.

"(2) No individual may be awarded the Medal unless at the time such award is made he—

"(i) is a citizen or other national of the United States; or

"(ii) is an alien lawfully admitted to the United States for permanent residence who (A) has filed a petition for naturalization in the manner prescribed by section 334(b) of the Immigration and Nationality Act and (B) is not permanently ineligible to become a citizen of the United States.

"(3) The Medal may be awarded posthumously, the provisions of paragraph (2) of subsection (b) of this section notwithstanding. The Medal shall be so awarded only to an indi-

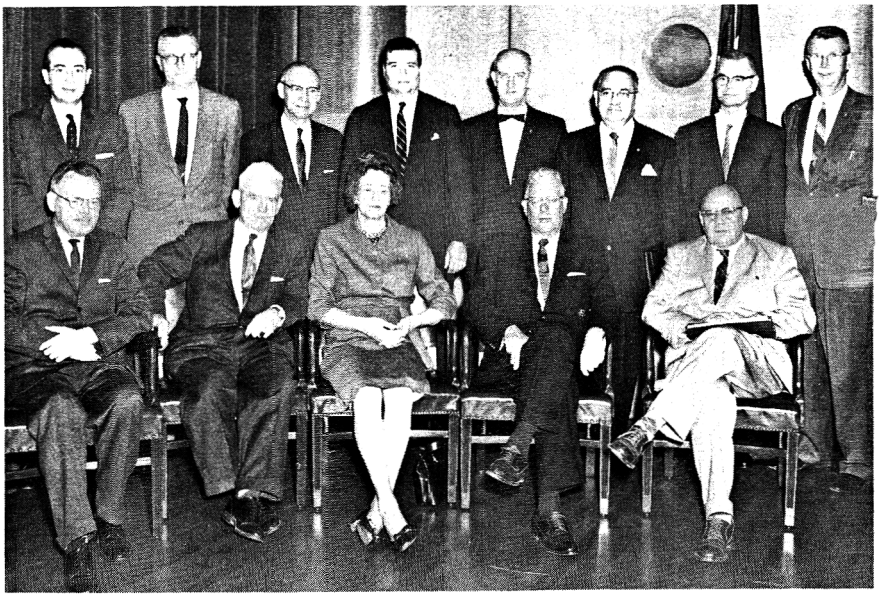
vidual who at the time of his death met the conditions set forth in item (i) or item (ii) of that paragraph and not later than the fifth anniversary of the day of his death."

Summary of Developments in HEW Under Eisenhower Administration.—With his letter of resignation as Secretary of Health, Education, and Welfare, Arthur S. Flemming submitted to the President a summary of the developments that have taken place in the fields of health, education and welfare under the leadership of President Eisenhower. It reads, in part, as follows:

"Soon after he took office, President Eisenhower recommended establishment of the Department of Health, Education, and Welfare to bring to the highest councils of Government the human problems of the people. The 83rd Congress approved his plan, and the first new Cabinet office in 40 years came into being in April 1953.

"In one way or another, the programs of the Department touch the lives of every man, woman and child in America. The goal of all these programs is to conserve and strengthen the Nation's greatest natural resource—its people.

"Since the Department was created, dramatic progress has been made in the national effort to achieve better health, better education, and greater economic security. The Administration has supported and obtained legislation to strengthen the Nation's educational system, broaden the coverage and the benefits of the Social Security Act, expand a rehabilitation program which offers new hope for the disabled, strengthen our research efforts in science



Among those who attended the 1960 Joint National Conference of FDA-FLI were the following (seated, from left to right): J. Kenneth Kirk, T. E. Sullivan, Ella H. McNaughton, Franklin M. Depew and Emil M. Mrak. Standing are Philip L. White, Bruce E. Ellickson, Charles Glen King, Richard S. Gordon, M. R. Clarkson, Bernard L. Oser, Winton B. Rankin and Franklin D. Clark.

and medicine, provide more adequate health services and facilities, and provide improved protection to consumers against harmful foods and drugs. This progress has been made within a policy of fiscal responsibility in the conduct of Government, and under programs designed to encourage greater initiative and enterprise by individuals, private agencies and local and State governments.

"Progress in Health

"In 1954, the first full year of the Department's operation, expenditures for the Public Health Service totalled $242 million. The President's 1962 budget calls for estimated expenditures of $1.001 billion—an increase of 314 percent. In the past seven years:

"1. Medical research has been vastly expanded, with particular emphasis on cancer, heart diseases, mental illness and other major killers and cripplers. Federal assistance to medical research has increased sevenfold since 1954. Major new research centers have been put to work.

"2 Health and medical facilities have been significantly expanded. The Federal-State program to assist in constructing hospital and medical facilities has been broadened to include chronic disease hospitals, nursing homes, rehabilitation facilities and diagnostic and treatment centers. A new grant program has been established to enable medical schools and other institutions to improve and expand their laboratories and research facilities.

"3. The supply of manpower skilled in the health sciences has been increased. Training grants and fellowships have been established, or expanded for promising research scientists, public health personnel, graduate professional nurses, and practical nurses.

"4. Greater emphasis has been placed on the promotion of public health and preventive medicine among the American people.

"Greater Food and Drug Protection

"Expenditures for the Food and Drug Administration in 1954 were $6.2 million. The President's 1962 budget calls for expenditures of $23.4 million—an increase of 277%. In the past seven years:

"1. Food and Drug Administration inspection force has been tripled since 1954 in order more effectively to guard the Nation's food and drug supply and remove unsafe products from the marketplace.

"2. Basic scientific research programs have been intensified, scientific staffs have been increased, laboratory equipment has been modernized, two new field headquarters have been established, and construction of a new headquarters building with modern laboratories has been authorized.

"3. Far-reaching legislation has been sought and obtained to improve the protection of the public against harmful, unclean or misrepresented foods, drugs or cosmetics. A landmark in this effort was the Food Additives Amendment of 1958 which required that food additives be shown safe for human consumption before use. This legislation established the principle that the burden of proof must rest squarely on the manufacturer to assure the safety of products prior to their sale to consumers.

"4. Administration-sponsored legislation was enacted in July, 1960 to provide a scientifically sound basis for approving colors that may be safely used in foods, drugs and cosmetics, and to establish other safeguards including, where necessary, appropriate tolerance limitations on the amount of the color that may be used.

"5. In addition, the Administration has proposed further amendments to the Food-Drug and Cosmetic Act to strengthen factory inspection authority, require manufacturers to make reports on clinical experience with new drugs, and assure adequate controls over the purity and quality of drugs."

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The United States Commissioner of Food and Drugs, George P. Larrick, is conversing, above, with William T. Brady, chairman of the board of trustees of The Food Law Institute, and, below, with Franklin M. Depew, president of the institute. They participated in the 1960 Joint National Conference of FDA-FLI in Washington, D. C., November 28 and 29.

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1960 Joint National Conference—FDA-FLI

Contributions of Technology to the Nutritional Value of Food

By CHARLES GLEN KING

The Author Is Executive Director, The Nutrition Foundation, Inc., and Professor of Chemistry, Columbia University. He Was Moderator of the November 29 Consumer Morning Session at the 1960 Joint National Conference of Food and Drug Administration and The Food Law Institute.

THIS CONFERENCE to review problems of material interest to the general public and to those who work in agriculture, government agencies, universities and the food industry is very timely. The topic for discussion is not narrow in any sense. In a greater degree than we sometimes realize, everyone is both a consumer and a producer. Accurate information to guide the consumer is essential to all parties, because the producer and distributor are always under the discipline of offering what the consumer will buy. All need to be reliably informed, and no one likes to be fooled. Very few people in modern society are without a direct influence on food that is produced and distributed as well as in meeting their own personal requirements and preferences in food consumption.

I am confident that there never has been a time when either the general public—commonly referred to as "consumers"—or those who

produce and distribute food were more conscious of their mutual interests and responsibilities than is true today. However, a great amount of confusion and misunderstanding has developed that can only be corrected by well-organized, honest, vigorous and sustained programs of education. This responsibility for reliable and interesting information to the public has been sorely neglected. The problem is not simple to solve. We need to find ways of protecting the public against misleading, wasteful and often dangerous information via the mass media, just as much as there is need to avoid false labelling or carelessness in the production of food commodities.

New developments from research in agriculture, in chemical synthesis, in the science of nutrition, in medical practice and in changing concepts of public health all contribute to the need for continuous and unbiased information to guide consumers, producers and distributors alike. Advances in research tend to be entirely in the public interest, but their application will always need to be safeguarded in terms of health risks and interpretation.

Undoubtedly the acceleration of research in recent years represents one of our greatest assets in reaching higher levels of health for the entire population, and specifically in relation to food practices. Hence it should be supported and encouraged in every reasonable way. Again, because of the complexity of the many factors involved, the adaptation of our new food, drug and cosmetic laws requires continued study and refinement as well as technical and lay interpretation. The primary issue of placing responsibility on food producers and manufacturers for the safety of the food supply is undoubtedly sound. It defines an area of responsibility that requires constant consideration and understanding among producers, distributors and consumers. There is need, also, for introducing an increased element of independent judgment and evaluation by scientists and public servants who can take an unbiased view with respect to the science aspects and broad perspectives in the public interest.

We have long since reached a stage in our "western culture" in which the chemical industry is an essential part of modern agriculture, food processing, food distribution and immediate service to the public. Chemistry is first of all a servant of the public, just as engineering, medicine, law and education are basic servants in almost every area of endeavor. The food industry at all levels shares in this mutual responsibility to protect the public on the one hand, and to be alert

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to new avenues of service in which the chemical industry shares with increasing efficiency and mutual interest.

I have often referred to food technologists as the "managing scientists of the food industry." In a real sense, this group of scientists has the major responsibility to be regardful of the public interest as well as to be diligent in taking every reasonable advantage that arises from progress in merchandising, as well as in fertilizing the soil, processing foods, research in genetics, and advances in the science of nutrition. They must guide the over-all flow of foods in serving the consumer and thus meet the challenge of a food supply adequate for mankind everywhere, with a minimum sacrifice of other cultural advances that society will demand.

Let us turn to some of the major areas where food technology has made great strides of progress, and where the public often expresses a feeling of uncertainty concerning where these modern developments have taken us in relation to health and in relation to an outlook for the future.

Advances in Identifying Relationships Between Plant Nutrition and Animal Nutrition

We often hear accusations that the nutritive quality of modern food supplies has been impaired by depletion from the soil of its normal plant and animal nutrients, and that this trend has been greatly accelerated by the use of chemical fertilizers. We hear less in the public press, however, of the great advances we have made in identifying the requirements for plant and animal nutrients in the soil, essential for food production, and the further great advances that have been made in identifying the relationships between plant nutrition, in which mineral elements play a dominant role, and animal nutrition, which is fundamentally dependent upon a great many organic nutrients formed in plants. This is an area where science has contributed so greatly to our modern requirements that it should be featured in educational concepts presented carefully to the public. The major points at issue may be summarized as follows:

(1) Farmers and manufacturers of plant foods (fertilizers) are, in general, very alert to the fact that care of the soil in every respect constitutes the dominant factor in securing good yields and good quality products. Their economic interest is not contrary to their best service to consumers.

(2) Most soil conditions that make possible high yields of crops are the same conditions that make possible high nutritive value, high resistance to diseases, and minimum deterioration during harvesting, processing and distribution. Hence, farmers are even more actively interested than consumers in such matters as soil erosion, poor availability of nutrients from the soil, and any advantages to be derived from organic material in the soil.

(3) Without continued progress in the study and use of manufactured plant nutrients, and in the use of manufactured materials to control pests, weeds, fungus diseases and animal infestations, it would be utterly impossible to meet present or future food requirements of our growing population, either here or in other parts of the world. Farmers and manufacturers do not question the requirement for diligent care in protecting human and animal health when such materials are used. In actual experience, the record on this score in America is very good. Hence, despite occasional unfortunate mistakes, the clamor against modern improvements in agriculture on this score is usually exaggerated and, on the whole, unfair to the public.

Two areas of research and practice merit special comment at this point. Studies of the mineral requirements for growth and health in plants and animals have permitted tremendous progress in food production through the use of balanced quantities of trace or micro mineral elements such as copper, iron, zinc, molybdenum, manganese, cobalt, fluorine and magnesium in recent years. Within the United States, there are vast areas where soil adjustments of this nature make a major contribution to the nutritive quality as well as to the yields of food and feed supplies. In California, for example, naturally deficient areas of this kind have been identified in every county, and in Eastern Washington, eight major crops are notably improved by adding small quantities of zinc to the soil. Many of the soils in North America that are now highly productive were actually less suited to agriculture and protection of human health in their primitive state.

Similar or greater gains are developing rapidly from research in genetics. These new crops are better adapted to environments where food production had been regarded as either normal or very unsatisfactory. Tomatoes, for example, are now moving into the subtropics and into northern areas where they could not be produced commercially before. This means better nutrition and more rapid economic progress in handicapped areas. In the search to find crops that give

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good yields, good shipping qualities, good flavor and good color, there is obviously some risk that one or more nutritive values will be lowered or not observed. The risk on this score is relatively small, however, because of the fact that mineral elements, vitamins and other nutrients tend to be high in plants which grow vigorously and have good resistance to disease. This trend fits the well-known pattern of remarkable similarity in all living things whether plant or animal. It is also true that many geneticists are working specifically toward the objective of increasing the nutritive value of key crops, as they have in hybrid tomatoes. Hence in an over-all picture, research and new practices tend to result in more food of higher nutritive value, rather than imposing a risk to the health of consumers. This fact was brought out forcibly in the recent Fifth International Congress on Nutrition held in Washington, September 1-7, 1960, during the symposium on "World Food Needs and Food Resources."

Food-Processing Problems

Another area of frequent misunderstanding is with reference to the processing of foods by such means as canning, pasteurizing, freezing, dehydration and packaging. In this respect there are obvious risks that require constant attention to retain nutritive quality as well as other essential features such as flavor, appearance, convenience and stability in the final products. On the whole, modern industries are much more conscious of risks of this nature than were our more primitive farmers and distributors before scientific practices came into use. Certainly the canning industry in America has been vigorous in its study of heating, storage, kinds of containers, and other factors that are important in the conservation of nutritive quality. Most processors have also gone to great lengths to assist farmers in growing crops of greatest value to the consumer, and in conserving these values by improvements in harvesting practices. Leading manufacturers, in cooperation with the National Canners Association, have conducted thorough nationwide studies of starting materials, processing practices and the related conservation of nutritive values in a great variety of canned foods. One study alone costs about $350,000. A fortunate coincidence in this respect is the general parallelism between practices that result in a product with good flavor, color, appearance and all-over acceptance qualities and practices that favor retention of unstable nutrients such as the vitamins, proteins and fats. Storage conditions are also important in this respect, and have received much attention

with respect to containers and delays in market flow from producer to consumer.

Again, in the frozen food industry, manufacturers have taken the initiative in comprehensive studies of varieties, environments, and processing conditions that would assure to the consumer, products of high nutritive value as well as convenience and public acceptance. Information concerning these practices has been made widely available to the public so that they can be accurately informed and to manufacturers so that they can be guided in their progress. During the past decade a nationwide study of this nature was conducted by the National Association of Food Packers at a cost of about $300,000.

In the management of fresh foods such as milk, meats and vegetables, there is also a general correlation between the characteristics of products on the market that make them acceptable and their retention of nutritive values as consumed. There are exceptions, of course, as illustrated by the tendency to harvest before maturity to gain advantage in stability of handling and in early market prices; and the public has a preference for many light-colored foods that have a lower nutritive value than those with more intense natural color. Substitution of artificial colors for natural colors can be misleading on this score, but in most instances labelling laws have required that the public be informed accurately.

Safety of Food Colors

Restudying the safety of food colors and other food additives unquestionably should be a part of continued progress. Long-term testing with experimental animals before new additives enter the food supply represents a trend that, in general, is welcomed by food technologists even though there are many detailed points of disagreement in regard to specific requirements and practices. The Food Protection Committee of the National Academy of Sciences-National Research Council has rendered an outstanding public service in this area. Its continued advisory service to government agencies, to industry and in public education can contribute a much needed feature of independent scientific judgment and sound reason.

Among improvements in the nutritive value of the public food supply based upon technological progress, there are many notable examples such as the gains in health that have resulted from the use

of vitamin D standardized milk products to eliminate rickets, iodized salt to prevent goiter, fluoridized water to prevent tooth decay, vitamin A in margarine to match the approximate value in butter, and the broad program of cereal enrichment to decrease the risk of deficiencies in iron, niacin, thiamine and riboflavin. There is still a considerable amount of anemia; but, according to the best recent evidence, very little of the anemia can be attributed to vitamin deficiencies, and only a small proportion can be attributed to malnutrition in any respect. The most important factors appear to be excessive blood loss and other stresses that are medical and not nutritional.

Need for Policies That Make Provision for Reason and Scientific Judgment

In a transition period of adjusting new laws and new research findings to best serve the public interest, it is not surprising that many difficulties have arisen that should have immediate and careful consideration. One of these features is with respect to the need for policies and regulations that make adequate provision for reason and scientific judgment. This point was well presented by the President's Science Advisory Committee, in furnishing a special report (1960) on food additives. Many representatives of the public apparently do not yet understand the fundamental requirement to consider nutritive values and the risks of injury from so-called toxic materials, as being essentially quantitative in their significance. The concept of "zero tolerance" and regulatory trends in that direction need special consideration. From a chemical point of view, and on the basis of abundant evidence, no informed person would question the fact that all nutrients should be appraised in regard to at least three levels or zones of concentration in relation to their biological and health significance.

Starting at the bottom of the quantitative ladder, there is a zone that applies to all nutrients and additives in which the quantity is so small that it is relatively insignificant in terms of either nutritive value or risk to health. As research progresses in methods of analysis and in biological testing, this zone can be increasingly well-defined; but denial of its reality or significance has no valid position in modern science. Secondly, a higher zone quantitatively will show a biological advantage in such terms as growth and health or, conversely, there will be evidence of a functional change or of injury in structure or in over-all health and vitality. A third quantitative zone then appears at a higher level at which there will be impaired function or injury to the

organism that can be demonstrated. This principle applies to essential and nonessential nutrient materials as well as to materials that are commonly classified as being useless or toxic.

In dealing with desirable or essential nutrients, then, scientists are deeply concerned with finding the first range in quantity at which a nutrient becomes of significant value, or a nonnutrient may become significantly injurious to the organism. In dealing with nutrients, whether essential or nonessential, one then needs to know both the approximate range in quantity that will demonstrate optimum physiological value and the critical zone above which there is evidence of injury.

Specific Examples

To cite some specific examples of the above three zones, and their relationship to food intake and agricultural practices, let us first look at the record for the last eight mineral elements discovered to be required for optimum human health. Each one of them had been studied for several decades biologically, almost solely because they had been found to be injurious to living organisms and hence were regarded as toxic or poisonous. Copper had long been regarded as a toxic element, and many forms of the element had been used in treating infections as a medical agent or in preventing growth of algae, fungi, molds and other organisms. Blue vitriol and copper sprays, for example, had been widely used. But in the 1920's, Dr. C. A. Elvehjem of the University of Wisconsin found that small amounts of copper—about one tenth of the requirement for iron—were necessary for the utilization of iron in forming red blood pigments. In view of the fact that copper is also essential for the normal development of plants, one will find some quantity of copper in practically everything that enters the human body. One is concerned primarily with the quantitative zone below which health would be impossible and the higher zone above which there would be toxic effects and injury or death. Essentially the same picture is clear with respect to the subsequent seven essential nutrients. Each element went through the same cycle of study, beginning with its toxicity; then, discovery of its requirement for health and the zone below which health was impossible; and last, a higher zone above which there was clear evidence of toxicity. Without going into details, these elements can be mentioned briefly as follows: manganese, zinc, cobalt, fluorine, molybdenum, selenium and—finally—this year, *chromium*.

Each of these elements must be appraised in a quantitative sense with respect to whether or not they can be described as "insignificant," "essential" or "toxic."

Now in reality, the point indicated above applies to practically everything we eat and to practically everything that appears in the soil as a factor affecting the development and vitality of plants. If we get into a situation of attempting to regulate food composition and practices with respect to chemical constituents on anything other than a quantitative basis, we will be moving in the wrong direction and apparently will be in a position that is untenable in terms of decisions of the Supreme Court, in which there is acceptance of the principle that our laws and their interpretation should be based on reason and judgment.

This issue is already forcibly before us, and should have urgent attention in the public interest. Otherwise, confusion will be increased, with resultant inefficiency and unnecessary difficulties for everyone.

Conclusion

In conclusion, there is no doubt that food technologists have a great responsibility to be alert and critical of the risks imposed on the quality and safety of their products by rapid changes in agricultural and merchandising practices. The potential health gains and cultural advantages to society are so great, however, that progress clearly lies in the direction of accepting the challenges.

An increasing emphasis on quantitative measurements and on quantitative concepts in biological interpretation will be urgently needed as a guide, both in research and in relation to regulatory practices. Otherwise, there will be unreasonable risks—risks to health at one extreme and risks of "paralyzing fear" at the other.

The same principle applies with reference to nutritive quality. Every clearly identified nutrient merits quantitative appraisal in food products with respect to health. In this area, too, new concepts are advancing steadily with respect to the quantity of intake and the length of time for significant changes to occur.

Our past success in health improvement applies with greatest force to the first three years of life. The sharpest challenge now is to add vigor and health to the 40 years above 45. **[The End]**

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Public Awareness of Health Aspects of Chemical Aids

By EMIL M. MRAK

In His Paper Before the FDA-FLI Conference, Dr. Mrak Emphasized That the Educational Information Put Out Has Missed Its Mark. "We Must Have Something That People Will Read, Enjoy and, Above All, Keep," He Said. He Is Chancellor, University of California, Davis.

I AM SOMEWHAT APOLOGETIC about discussing this subject to a group such as the membership of The Food Law Institute. I am certain that members of this organization are well informed of the public health awareness of health aspects of chemical aids. Nevertheless, I wouldn't be honest if I didn't say I was flattered when invited to address you. I would like to restrict my discussion to some experiences we have had in California during the past year.

Factors Contributing to State of Confusion

After the passage of the Miller bill and the new food additive bill, I had an occasion to talk with many members of the food industry concerning the possible effects of these laws on the food industry. It was difficult, if not impossible, to realize the far-reaching implications of these bills. As a whole, the canners, dried-fruit people, dairy people and others considered them as comprising good legislation, although there was genuine concern about the Delaney clause.

None of the industries with which I discussed the matter could realize or visualize the far-reaching effects, whether they would be direct or indirect. It was difficult to visualize the effect that one industry might have on another. Furthermore, it was difficult to realize the effect on the food industry of publicity that might be directly or indirectly related to the new laws.

It is apparent to me that the adverse publicity received by some food industries has in one way or another affected the others. Most certainly it has had some effect on the public confidence in our food research and control agencies and the organizations responsible for a good food supply. It has directed a unilateral type of thinking such as "all foods are poisonous," or "processing is bad," "we must do away with pasteurization," etc. I am certain no well-informed person would favor abandoning pasteurization. Other types of thinking that have come to my attention are that processed foods are not nutritious, all agricultural chemicals are bad, our scientists are pseudoscientists, the university and research scientists are involved in one way or another with the chemical industries, etc. I would say that this has been our psychological environment for the past year.

Another factor that has contributed to a state of confusion is the existence of differences between state laws and those of the federal government.

DDT Found in Dairy Products in California

During the past year, some occurrences have taken place in California that may be of interest to you. The Food and Drug Administration found DDT in butter and evaporated milk shipped out of our state. It is needless to say that when this observation was made, the dairy industry was concerned and anxious to do something about it. Questions immediately arose: Where did the DDT come from? How could it be determined? Would it be possible to work out a simple procedure for determination that might be used at the farm or creamery level? How could such occurrences be prevented in the future? Meetings were called where the matter was certainly discussed at length and forces were mobilized to cope with the problem. These included the California Agricultural Experiment Station, Agricultural Extension Service, State Department of Agriculture, State Department of Public Health and the State Legislature.

It was also apparent that one of the factors involved in the problem was the existence of a tolerance of 7 p.p.m. for DDT on hay produced in California. When this tolerance was set, it was not generally known that the halogenated hydrocarbons would be concentrated in the fat of the milk. It is well known now, however, that

when a cow feed is contaminated with DDT or related compounds, the material will be concentrated in the fat and when the milk is converted to butter or evaporated milk, the agricultural chemical concentrates accordingly. This, then was the real problem.

It was found, however, that hay was not the only problem. Other feeds such as dry tomato waste, dry bean vines, refuse from seed alfalfa, apple pomace and other materials actually contain DDT, and it was necessary to recommend against the use of these items for feed for dairy cows. Then, too, there was a factor of drift from airplane spraying. This problem has been studied, and great strides have been made toward minimizing drift contamination of adjacent fields of alfalfa and other dairy cow feed. Furthermore, there was the possibility of overapplication on the part of some farmers. This, too, has been corrected.

The Experiment Station has worked out a method for the rapid detection of DDT that might be used at the creamery. Short courses were held to teach technicians methods of analysis for these substances. The Agricultural Extension Service held meetings from one end of the state to the other to apprise farmers and others of the procedures to use and control measures to employ. As a result, the situation has improved tremendously in a matter of only a few months.

Work of Fact-Finding Committee

Nevertheless, the governor considered it desirable to appoint a committee to study the state policy with respect to agricultural chemicals. This fact-finding committee consisted of the dean of the Statewide College of Agriculture, a dairy farmer, a member of the Farm Bureau, the state consumer counsel, the director of the State Department of Public Health, the state director of agriculture, a canner, a food processor, a toxicologist, a member of the medical association and two home economists; I was appointed chairman. The chief of the San Francisco District of the Federal Food and Drug Administration was invited to participate as a consultant and advisor. He was most helpful in the deliberations of the committee.

The committee had four full days of hearings, two of which were in Sacramento, one in Berkeley and one in Los Angeles. The committee invited people to present material and, in as far as possible, permitted those who wished to make presentations to participate.

including guests in attendance. There will be one or two more meetings during which time a report will be prepared for the governor.

Some Highlights of Committee Meetings

The hearings involved a great many pages of testimony, and it would not be possible to review all the material thoroughly at this time. I would, however, like to present a few of the highlights of these meetings. At the first meeting it was pointed out that agriculture in California is a $3 billion industry involving 139 major crops and about 110 minor crops. The dairy industry amounts to $376 million and cotton, $346 million. The pesticides used in California are valued at about $100 million; and 14,867 different items are registered, a great many of which are household and garden pesticides. In 1959, the pest control operators treated 7¼ million acres, and the farmers treated about 5 million acres. Because of this, we have stringent laws in California concerning the use of pesticides, and these are enforced through the State Department of Agriculture.

A representative of the State Department of Public Health stated it would not be possible to maintain the healthy, rewarding, outdoor type of living in California if we didn't have the benefit of pesticides. Furthermore, the director of public health acknowledged the benefit to agriculture of pesticides. He pointed out that chemical illness in agricultural workers was considerable and in 1959 amounted to 1,100 cases. There was some discussion about the relation of chemicals to wildlife and dogs. This is, of course, a general controversial area. Water pollution is a real problem, one that will require further study and consideration.

Statement by State Consumer Counsel

The consumer counsel presented a statement which is interesting and reads like this:

> On behalf of consumers, I want to thank each of you for agreeing to assist in formulating our public policy on the use of agricultural chemicals. I can tell you many mothers and homemakers have gained some reassurance already from the fact that this committee has been formed and will be deliberating.
>
> It is literally true that the policy developed here will vitally concern every family in California.
>
> Of all the many concerns and anxieties that mothers and housewives have expressed to me as their Consumer Counsel, none is more universal and none is

the cause of as much generalized anxiety and frustration as that of the concern over harmful chemicals in our food.

The housewife's fear of agricultural chemicals is a fear of the harmful, unknown, and unseen. Her frustration arises from a feeling of utter helplessness to do anything on her own to protect herself and her family.

Today the homemaker finds herself in an intolerable paradox—she is more highly educated, better informed, with a higher income, and more aware of her responsibility for her family's health than ever before. Yet, she has never felt less certain that her own efforts can guard her family's good health.

She can study Dr. Spock, visit her pediatrician regularly, and sterilize the milk bottles carefully—but there is nothing she can do, herself, to make sure that the milk in the baby's bottle contains only healthful, pure nutrients and no harmful pesticidal residue. She is helpless here and she knows it.

She can wash salad greens thoroughly and keep them crisp and fresh—but there is nothing she can do, herself, to make sure that the salad greens she serves her family for dinner provide health-building vitamins and minerals and no harmful agricultural chemicals.

She can carefully save the cooking waters from vegetables, but when she makes them into soup, there is nothing she can do, herself, to make sure that the soup contains only health-giving ingredients and no harmful agricultural chemicals. Again, she is helpless and she knows it.

She can be sure, she can be free of some of this frustration and much of this fear only through the enactment of a public policy in which she has confidence and enforcement of that policy by people in whom she has confidence.

Need for Positive Publicity and Education

This is a strong statement and certainly indicates a situation that borders on fright and terror. It causes one to wonder if the gains obtained by careful application of our food protection laws might not be lost because unnecessary and adverse publicity has developed of neurotic and fearful individuals. It indicates quite clearly the need for positive publicity and education. As a matter of fact, the thread that ran through all the hearings indicated quite clearly the need for education and, above all, dignified education. The testimony of the home economists and members of the medical profession added to the strength of this thread. It is apparent they are anxious to have information presented in a concise, dignified and usable manner, and that the publications ordinarily available are long, boring, poorly prepared, and difficult to use. The format is generally uninteresting and, as one physician indicated, it makes it very easy to file the material—in the wastebasket. If we are to approach home economists, schoolteachers, the medical professions and others with literature, we must prepare

it in such a manner that it will accomplish its purpose. One doctor testified that he nearly always throws the literature he receives in the wastebasket, and yet he felt the need for information. He pointed out that any pamphlet should be so well prepared and of such quality that it would be difficult to throw it away. Furthermore, he indicated that the amount of printing should be at a minimum, and the number of illustrations, diagrams and brief tables should be at a maximum. Above all, the information should be positive rather than somewhat apologetic. I personally know of little, if any, information pertaining to agricultural chemicals or food additives that fits this description. The home economists testified they would also like such information, and indicated that it should be dignified and geared to their level.

Importance of Use of Chemical Additives in California

There was further testimony concerning the importance of the use of chemical additives in California and the present losses from agricultural pests. It was pointed out that the losses from all pests in the world amounted to $8½ billion which could purchase the crop from 88 million acres. The acreage in production in the United States today is about 358 million. California losses are extremely high: From weeds alone the loss amounts to millions per year, from plant pathogens it amounts to $100 million per year, and others are substantially high. California uses about one fifth of all the pesticides sold in the United States.

Viewpoints of Agricultural Chemical Producers and Agriculturists

The second meeting was concerned with the points of view of the agricultural chemical producers and agriculturists. Representatives of Organic Ville and those who oppose the use of agricultural chemicals made presentations. The increase in deteriorative diseases such as cancer, diabetes and cerebral palsy was related to the increased use of agricultural chemicals. It was stated that agricultural chemicals inhibit the production of plant enzymes and complete protein formation and, hence, affect the human who may eat these plants. It was further indicated that adverse effects might appear in the teeth and muscles of children. Finally, it was stated that the woman purchaser should be

able to choose whether she prefers worms or chemicals. Some of the views presented at this meeting were very positive and strong, and even resulted in a display of emotions. This was particularly true with respect to the use of DDT. Reference was made to the work of Dr. Hayes of the Communicable Disease Center in Atlanta, Georgia.

As a result of this, it was suggested that he be invited to testify at a future meeting. This was done, and Dr. Durham, one of his colleagues, spoke in his place at a later meeting. Dr. Durham's statement indicated that considerable work has been done on DDT and that in many instances it reaches a storage equilibrium in about one year. He further indicated that there was no evidence of toxicity.

Statements by Dr. Darby of the Food Protection Committee indicated that we could expect to be a food-deficient nation in the next ten or 15 years if our production remains at the present rate and if the same number of acres remains in production. Furthermore, he challenged a statement made on the effect of change in plant protein on the human organism.

Statements were also made concerning the need for the use of chemical additives, the extent to which the National Institutes of Health is supporting research in the area of toxicology, and the work of the state in connection with control programs and chemical residues. A great deal of information was presented concerning the Food and Drug Administration.

Further testimony by home economists indicated that in one large journal there were no inquiries about the use of chemicals in foods. On the other hand, a home economist representing a chain-store operation stated that they do have questions. Many of these relate to organically raised foods.

Failure to Communicate

In summary, it may be said that the most important thread running through all of the hearings relates to the failure to communicate. The educational information put out, therefore, has missed its mark. There has been a great deal of talk among the scientists and those concerned with food and chemicals, but this has not even reached the professional people who should have the information. Much has been published for scientists and those interested in the field but not for the professional layman. Further information is being published, but for whom I don't know.

It is apparent that we must have something that people will read, enjoy and, above all, keep. The Agricultural Extension Service can help but will need simple, usable information. On the one hand, we must help the medical people, home economists and schoolteachers. On the other, the farmers, the dehydrators of hay, and feed purveyors should be presented with another type of information. Processors as well as the manufacturers of chemicals can help in these cases.

Programs indicating what is being done by the Food and Drug Administration and the food industry are urgently needed. Although the program of Mrs. Williams of the Food and Drug Administration has been operating with increased activity for a relatively short period of time, it is having a positive effect. On any number of occasions during the hearings in California, home economists indicated to me how much they learned by visiting the laboratories of the Food and Drug Administration in San Francisco during one of the consultants' meetings. They stated quite clearly that they had no idea of the extent of the work and activities of the Food and Drug Administration. It was quite surprising to me to learn that there is a need to indicate not only what the processors are doing but also what the Food and Drug Administration is doing.

Conclusion

We need a long-term program on a multiphase educational basis. It must be made plain that our control and experimental agencies need further support, and this support should be forthcoming year after year. We must think in terms of interrelationships. We need a full-spectrum type of thinking.

We should proceed carefully and, above all, with dignity. We must create a climate of confidence on the part of all concerned with the safety of all foods, and we must support and control the research agencies to the hilt.

On the other hand, we must not create a false sense of security or fear. We should not create a climate for neuroses or we may well destroy the good we do, on the one hand, while creating the need for further support for mental health, on the other hand, and finally form the basis for another chapter in an exciting book written by McKay about 100 years ago entitled *Extraordinary Popular Delusions and the Madness of Crowds.* **[The End]**

Protection of the Nation's Food Supply

By M. R. CLARKSON

"We Do a Pretty Good Job of Reporting the Results of Research but . . . a Poor Job of Interpreting Their Significance," Dr. Clarkson Told Those Who Attended the Consumer Morning Session of the FDA-FLI Conference. He Is Associate Administrator of the Agricultural Research Service, Department of Agriculture.

A FEW MONTHS AGO our moderator, Dr. King, told a symposium that "no nation in history has had a food supply that would compare with our present supply in terms of nutritive value, safety, convenience, stability, variety, attractiveness, and availability."

Other experts have said the same thing. The fact is so widely accepted that no one rises to dispute or challenge it.

Why is this so? Just why are we blessed with abundant supplies of quality food, high in nutritive value, and unmatched for wholesomeness and safety?

Several factors account for this enviable position. First, of course, as a nation we are rich in the natural resources needed for abundant food production. Second, technology has contributed time- and labor-saving machines and new techniques. Third, research has given us new strains of crops and livestock that are superior to earlier ones in yield, quality and hardiness, and new means for controlling some of the more serious diseases and pests that seriously damage our food. Fourth, state and federal departments of agriculture have eradicated many dangerous and costly diseases and pests, or brought them under control. Fifth, regulatory agencies have assured consumers of wholesome food supplies by setting and maintaining high standards of safety and wholesomeness.

The wealth of our nation's resources is so well known as to need no elaboration. But it is quite obvious that this is only a part of the answer, for many other nations equal or exceed the United States in natural resources.

Time- and Labor-Saving Machines and Techniques

Our second factor, the technological revolution in time- and labor-saving machines and new techniques, derives from knowledge that is available throughout the world. It is true that our country has led in the development of a great amount of this knowledge, but we have no exclusive claim to it. It is the rapid adaptation and broad application of technological improvements to the solution of the problems of food supply that have been the distinguishing marks of this country.

During the last 20 years the labor productivity of workers in manufacturing, trades and services increased about 50 per cent. As a nation we are justifiably proud of the worldwide recognition of this achievement. It is not nearly so widely recognized that during this same period the productivity per man-hour of farm workers increased about 134 per cent. That is more than 2½ times the increase for workers in industry, trades and services!

This increase has meant lower food costs for consumers. It has meant the release of farm labor to industry and defense to keep the nation strong. Unfortunately, the farmer himself has not benefited as fully as the city worker from increased efficiency. The farmer's returns from his labor, his management skills and his capital outlay have not kept up with those of his city cousins.

New and Improved Strains of Crops and Livestock

Third, research by industry, the universities and government has given the farmer new and improved strains of crops and livestock. Even so, research has barely kept up with the requirements of farmers for hardier, disease-resistant plants and animals. The need for quality improvement accounts for some of the research achievements, but the devastations of pests and diseases make many of them mandatory.

For some of our crops the build-up of diseases has been so rapid and intense that all of the commercial varieties grown just 20 years ago have had to be replaced with newer, more resistant strains. The ability of rusts, viruses, smuts and other disease organisms to adapt

to new varieties, and to overcome changes in growing practices, presses hard on the heels of the farmer and the researcher. In some cases, as with pear decline on the West Coast in 1960, the disease is well out ahead.

It has been said that, as the numbers of animals in a given area increase arithmetically, the incidence of disease increases geometrically. This further emphasizes the demands on agriculture to meet the enlarging food needs of a rapidly increasing population. These needs must be met from the same number of acres used to produce our food 40 years ago.

Some of the most dramatic advances from research have been in the uses of chemicals to aid in the production, utilization and marketing of foods. Although chemicals have been used for these purposes for centuries, it is only recently that their role has been understood. With understanding have come better chemicals, more precise application and improvements in safety. From fertilizers to fumigants, chemicals play a vital role in the production of safe, high-quality food.

Control and Eradication of Diseases and Pests

The fourth point in the list of major factors affecting the characteristics of the food supply is the control and eradication of diseases and pests by state and federal departments of agriculture. It is because of these activities that consumers in this country do not find the larvae of Mediterranean or Oriental fruit flies in their fruits, or the germs of tuberculosis in their meat and milk. These and many other diseases and pests have been eradicated or closely controlled. We enjoy the benefits each time we sit down to eat.

Activities of Regulatory Agencies

My fifth point is concerned with the food protection activities of regulatory agencies. Here, again, the position of the United States is pre-eminent. The experience and ability of our experts in this field are unsurpassed. From the 1906 passage of the Food and Drug Act and the Meat Inspection Act there has been a steady improvement in the scope and effectiveness of the general surveillance over the wholesomeness of the food supply.

The activities of the Food and Drug Administration are well covered at this conference by representatives of that agency. I will

comment briefly on some aspects of the meat and poultry inspection programs.

The Meat Inspection Division of the Agricultural Research Service is under the leadership of Dr. Clarence H. Pals. Dr. Pals is well known in the food industry and has a distinguished record of service in the department.

The Meat Inspection Act and the new Poultry Products Inspection Act give the Secretary of Agriculture broad powers to inspect all the products of packing plants from which any portion of the meat or poultry is to move in interstate or foreign commerce.

Meat inspection begins with ante-mortem and post-mortem examination for disease. It carries through to control of the processing, packaging and labeling to assure consumers that the meats and their products are safe, wholesome, free from disease and adulteration, and properly labeled.

The Meat Inspection Division's approval must be obtained for packing plant construction, equipment and operating procedures. All operations are under the scrutiny of trained inspectors.

All ingredients, including chemicals and other additives, must have prior approval by the division before they can be used. The primary controls exercised by inspectors in the plants are supported by chemical and biological laboratories.

The round purple stamp "U. S. Inspected and Passed" is the symbol of safety and wholesomeness for meats and meat products.

The record amply demonstrates that these activities and those of the Food and Drug Administration have maintained the consumer's confidence in the food supply. But, to quote Dr. King again: ". . . the attainment of this goal, however, does not . . . mean that still greater progress cannot be made in the years ahead."

Legislation

Sound legislation is a basic requisite for good administration. The laws passed by the Congress must be faithfully carried out. As experience shows that changes are necessary, appropriate recommendations must be presented to the Congress for consideration. As Mr. Justice Holmes said, in commenting on the Common Law: "The life of the law has not been logic—it has been experience."

Food control laws should set forth basic standards and provide ample authority for enforcement. They should give the responsible agency authority to exercise sound administrative judgment, taking into consideration all available scientific and professional information. Sound administration of food control laws should be unhampered by the pressures of special interests, partisan politics or emotional appeals.

Legislators and administrators alike need the benefit of expanding knowledge that comes through research. The fields of research that need additional effort are too numerous to mention here, but I would like to bring to your attention three areas that the Agricultural Research Service has placed in top priority:

(1) More basic research in human nutrition to provide guidelines for food and agriculture programs.

(2) More research to develop new and improved ways for controlling agricultural diseases and pests without leaving questionable residues.

(3) More trained scientists, up-to-date facilities and laboratory equipment to carry out the advanced research needed.

It was Heraclitus in the Sixth Century B. C. who was first reported to have said: "There is nothing permanent except change." This is certainly true today in the advancement of scientific knowledge.

Reporting Results of Research

We do a pretty good job of reporting the results of research, but in my opinion we do a poor job of interpreting their significance. We become so engrossed in the numbers game of percentage points, parts per million or parts per billion that we forget the critical problem of interpreting the significance of relationships of these terms when they concern the amounts of a particular material for a specific use. This is especially important in discussions of trace amounts of materials that appear in food or feed as additives or that may occur naturally in certain products. The basic question is much broader than one simply of presence or absence of a material.

These are some of the considerations that point up the need for re-emphasizing the goals in food safety to which this country is entitled and to which the Department of Agriculture is committed. We need to rededicate our resources—brains, dollars and facilities—to achieve those goals. **[The End]**

Medicine's Interest in Federal Legislation

By PHILIP L. WHITE

Dr. White, Who Is Secretary of the Council on Foods and Nutrition of the American Medical Association, Presented This Statement at the 1960 Joint National Conference of the FDA-FLI on November 29.

THE AMERICAN MEDICAL ASSOCIATION has followed the development of our present Food, Drug, and Cosmetic Act and its amendments and interpretations with great interest and at times with great concern. In the early days of the Act, the Council on Drugs and the Council on Foods and Nutrition were very active in promoting good and sound concepts relating to the interpretation of the regulations. More recently the Committee on Pesticides of the Council on Drugs was active in the support of legislation concerned with spray residues. The Committee on Toxicology had, for the past few years, sponsored a model law for the precautionary labeling of hazardous substances in commercial, household and industrial chemical products.

The law that was passed (P. L. 86-613) resembled the AMA model bill in many respects, although it is limited to the labeling of household chemicals. The Council on Foods and Nutrition was one of the groups that was instrumental in the formation of the Food Protection Committee. The AMA, then, has for some time actively supported the development of sound food, drug and cosmetic legislation.

The Council on Foods and Nutrition has proclaimed for years that there should be adequate pretesting of food additives, that additives should be employed only when justifiable, that an additive should not replace a more natural component of food that itself makes a nutrient contribution, that nutrient dilution should be avoided and

that, above all, there should be accurate and informative labeling of foods.

This summer both the Council on Drugs and the Council on Foods and Nutrition endorsed the President's Science Advisory Committee Report called the "Report of the Panel on Food Additives." Thus, the AMA supports the recommendation for the appointment of a board advisory to the Secretary of Health, Education, and Welfare as well as the other recommendations contained in the report. The AMA supports, in principle, legislation the purpose of which is to safeguard the food supply and to safeguard those who provide our food from accidental exposure to hazardous materials. Very few organizations will agree that the present wording of the law is perfect, particularly that portion referred to as the Delaney clause. The House of Delegates of the AMA has called for a review of the legislation concerned with foods and cosmetics. The study is not completed; consequently, I am unable to refer to it.

Wisconsin Report

The Delaney clause in the 1958 amendment has been the subject of many symposia and reports; a lot has been said about it, not all of which was complimentary. From my point of view, one of the most encouraging reports is that of the Special Committee on Chemicals and Health Hazards prepared for the Governor of Wisconsin.[1]

The Wisconsin report recommends that there be support of research, especially toward the establishment of tolerances, and also recommends "the substitution of a less rigid regulation providing that no substance with the ability to induce cancer following ingestion by man or animal could be employed in foods or appear in foods unless a safe level of use can be established through research and through evaluation by a properly qualified board of experts."

The report emphasized the importance of following labels and of educational programs to warn and advise the public and producers that pesticides and feed additives be employed according to established procedure and that only through proper use can safety of the applicator and the consumer be assured.

[1] Report on Food and Feed Additives and Pesticides, State of Wisconsin, Governor's Special Committee on Chemicals and Health Hazards, Madison, Wisconsin, April, 1960.

The Wisconsin report went on to recommend prior notification of any sudden changes in the regulations governing the use of feed additives and pesticides, and that the agencies involved provide regular releases telling of their activities. Further, the committee recommended that all agencies act to counteract misstatements and to counteract malignments of competent workers. It was especially enthusiastic in its recommendations that adequate funds be provided to greatly increase research and control. To this I add a hearty amen.

Problems to Be Solved

There are still a number of problems that need to be solved and some cloudy situations to be clarified. May I simply list a few of them?

(1) There is need for a standardized system of nomenclature for chemicals used in foods.

(2) Not all states have adopted adequate or standardized food, drug and cosmetics laws. Only 37 of the states possess food laws which are essentially identical to the consumer protection provisions in the federal Act and the vast majority of states have inadequate means of control.

(3) The problems inherent in toxicologic testing are considerable, and to the small company must seem insurmountable. Dr. David B. Hand has recommended the formation of an organization of the food industry with the assignment of dealing with all problems concerning the protection of food safety.[2] According to Dr. Hand: "Such an organization working closely with government agencies and independent scientific groups would be able to contribute to the interests of the public not only in safety but also in a continuation of technological progress." Such an organization could function to assist in the testing of food additives for safety.

(4) One of the serious problems is presented by the complexity of both qualitative and quantitative analytical methods. Related to this is the problem of determining levels of no or insignificant biological activity for hazardous compounds. These problems are both involved in the establishment of tolerances. A case in point is DDT

[2] D. B. Hand, 7 *Food Technology* 386 (1953).

in milk: Should tolerances for DDT be established between the limits of quantitative analytical sensitivity and biological insignificancy?

(5) The problem of unintentional contamination of foods and feeds with economic spray residues is serious, especially as the result of the widespread use of insecticides and herbicides.

Conclusion

In conclusion, the AMA is sympathetic to the need for refinements in our food, drug and cosmetics legislation and feels that progress towards this goal should not be hampered by undefinable expressions and concepts. Nor should legislation in any way inhibit the proper progress and development of our food industry. The AMA endorses efforts to provide good information to the public that will properly advise and reassure of the wholesomeness of our food supply. At the same time, it is imperative that educational efforts be expanded to reach all people—at home, in industry and on our farms—to remind them of the proper use of hazardous materials and to remind them to religiously follow label instructions.

[The End]

VOLUNTARY ACTS BY INDUSTRY TO IMPROVE CONSUMER PROTECTION

More than 238 tons of food were voluntarily destroyed or converted into animal feed by 236 owners during December after FDA inspectors had pointed out that shipments would violate the Federal Food, Drug, and Cosmetic Act.

Of this, over 50 tons were root beer or root beer concentrate containing safrol or oil of sassafras, a flavoring agent recently banned by FDA because it was found to cause liver cancer. Small quantities of the flavoring agent on hand for manufacturing use were also destroyed. Eighty-eight firms destroyed these materials in the presence of inspectors.

One hundred tons of cabbage harvested from a 20-acre field were plowed under because the field had been erroneously dusted with a DDT-Toxaphene mixture when the cabbage was mature. The cabbage showed double the residue of the pesticide dust permitted by the FDA tolerance regulation.

Twenty plant improvements at a combined cost of $383,200 were reported by FDA inspectors. A large flour mill, found on inspection to have an insect-infested elevator, spent $250,000 on cleaning, repairs and replacement of equipment. The old wooden floor was replaced with a tile-covered concrete floor, and hundreds of old wooden spouts were replaced with metal spouts. Several bakeries installed new tile flooring and equipment that would not harbor insects. A pickle factory rebuilt its floors to provide for better drainage, and provided lids for its brine barrels. Some of the improvements made at the suggestion of FDA inspectors were very nominal in cost, such as the installation of new screening and wire cloth to keep out insects, birds and rodents.

The Desirability of Uniformity Between State and Federal Laws on Food Additives

By T. E. SULLIVAN

The Big Question Facing the States, According to the Author, Is Not the Desirability of Uniformity Between State and Federal Laws but Rather How to Accomplish It. He Is Director of the Division of Food and Drugs, Indiana State Board of Health.

I AM HAPPY TO HAVE THE HONOR of participating in this 1960 Joint National Conference of the Food and Drug Administration and The Food Law Institute because it gives me an opportunity to bring to your attention some of the problems that face state and local regulatory agencies in their efforts to keep abreast of the increasingly complex problems which face them in the administration of their respective laws and regulations and in utilizing the more effective tools which have been developed by other agencies and which are applicable to their own programs.

The subject assigned for my part of this discussion is on the desirability of uniformity between state and federal laws on food additives. This specific area was chosen under the general title that appears on the program, "Current State Food Law Developments," because the question has been raised as to whether it is desirable or even necessary to maintain uniformity between state and federal food additive laws and regulations.

Value of Uniformity of Laws

I believe this question can be answered briefly and emphatically in the affirmative. I believe, further, that the same answer can be

given if the question were expanded to include pesticide residues on foods or color additives to foods. It seems obvious that, once a scientific basis has been established for (1) the need for controlling the quantities of certain chemicals that are added to our foods or the pesticides that are used on them, or the artificial colors that are used in them, and (2) the proportions of either that can be used to accomplish the agreed-upon desired result without injury to the consumer's health or his pocketbook, then the resulting standards should be recognized everywhere. Furthermore, the states recognize that it is in their economic interest to do so. They can thereby take advantage of the expense and time-consuming scientific work that has already been accomplished, and eliminate the extensive hearings and court tests which precede the final acceptance of regulations. Most of the states do not have the money, manpower or facilities to do the type of research necessary to the development of equitable standards.

Finally, the states realize that if each of them had the facilities to develop and enact their own standards, there would be unavoidable differences between each state's final law or regulation that would not only hamper inter- and intra-state distribution of articles subject to the varying standards, but would pose insurmountable administrative, legal and enforcement problems to the states themselves. I believe it can be said, therefore, that there is no question of the desirability of uniformity between state and federal laws dealing with food additives, pesticide tolerances, colors or, in fact, any other area where state and federal food and drug laws impinge.

The big question facing the states is not the desirability but rather how to accomplish it. The heart of the problem lies in the facts that basic laws, constitutions, traditions and interests differ from state to state, thus making it impossible in many instances for states to "lift" the language of a federal statute and insert it verbatim within the framework of their own state statutes. The Association of Food and Drug Officials of the United States has had a continuing program of promoting uniformity of federal and state laws and regulations. This is an organization, as many of you know, consisting of local, state and federal food and drug regulatory agencies and representatives. It has been a potent force in bringing about more effective and more uniform programs between the several states and between states and the Food and Drug Administration. Since 1939, it has been promoting the adoption of uniform state food and drug laws and

regulations. Despite all of its efforts, however, 22 years after the enactment of the present Federal Food, Drug, and Cosmetic Act, only a little more than half of our states have adopted state laws patterned after, and basically uniform with, the federal Act. The balance of the states have laws patterned after the 1906 Federal Act or have their own laws which conform to neither the 1939 nor the 1906 Acts.

Why Some States Delay Adopting Uniform Laws

Why are some of our states slow to adopt uniform laws? It would appear to be caused by the differing interests, traditions and problems that exist in these states; by the failure of the consuming public in those states to insist that the state law and the regulatory agency be given the tools to do a more effective job; and by the failure of the regulated industries themselves to support the need for modern legislation and well-staffed regulatory agencies. There have been instances in which industry has opposed uniform legislation or a more effective state administrative agency in the mistaken idea that it would be too costly for them to discharge their responsibilities. There have been other instances where a lackadaisical consuming public has failed to support needed legislation or even appear at hearings where the subject was discussed.

The fact is that those who are administering outdated state laws are seriously handicapped in obtaining uniform laws without the support and cooperation of the food, drug and cosmetic industries and of the consuming public whose health and welfare are affected by them. Without such support, representatives of the state regulatory agency are in the uncomfortable position of being suspected of catering to their own interests regardless of how much evidence they produce to demonstrate the need for modernizing their laws or enacting new ones. They hesitate, therefore, to "go it alone" and, consequently, nothing is done.

How, then, is it possible for those states that do not have uniform state food and drug laws to achieve the "desirable" uniformity of food additive standards? It would seem that the "desirable" goal is for the industry representatives and the consuming public of those states to join with the state agency in promoting the enactment of

recommended uniform state food and drug legislation, including authorization for the state to adopt uniform food additive, pesticide and color additive standards as they are developed and applicable.

Other Problems in Adoption of Federal Standards

Even where states have uniform food and drug legislation, many other problems exist in the adoption of federal standards. In some states, there is no provision which authorizes the administrative branch of government to adopt standards by regulation. In those states, the legislature itself must adopt the standards. Since most state legislatures meet biennially and since federal regulations dealing with food additives and pesticide tolerances (and, in the future, with color additives) are promulgated almost daily and may be changed frequently, it is a practical impossibility for the state to maintain uniformity, much as it may desire to do so. It would seem, therefore, that there is a need in some of our states to enact legislation which will delegate necessary powers to the administrative branch of government to adopt applicable tolerances, standards and regulations to keep the state law up-to-date.

Most of the state food and drug laws have in them the so-called "per se" rule—that no added poisonous or added deleterious substance may be used in or on a food unless its use is necessary in the production thereof or cannot be avoided by good manufacturing practice, in which case the state is required to promulgate regulations limiting the quantity therein or thereon to the extent it finds necessary to protect public health. This, as you know, is the same provision of the federal law that was replaced by the current food additives amendment. Although most of the state people realize that their "per se" rule is today ineffective because of the impracticality of developing the necessary proofs of toxicity and need for the hundreds of substances in use, some feel that the federal law, as amended, opens the floodgates for the use of chemical substances, some of which may not be in the public interest, and they will be forced to accept them if they amend their laws by adopting federal language *in toto*. Many others feel that the federal language will hamper their handling of problems peculiar to their own state or area. They feel, therefore, that special language is needed to fulfill their needs. States attorneys of some of the states have raised legal questions concerning the adoption of federal language in those states.

All of the states would like to have language developed which can be adopted by the states which will enable them to keep their state regulations or standards uniform with the federal act while at the same time permitting them freedom of action to handle problems peculiar to their states or to regulate empirically the use of substances which have been found to be misused or against the public interest in those states.

Proposed Amendments to Recommended Uniform Bill

In an effort to accomplish this, the General Counsel's Office of the Department of Health, Education, and Welfare, at the request of the Council of State Governments, drafted some proposed amendments to the recommended Uniform Food, Drug and Cosmetic Bill which the Association of Food and Drug Officials of the United States fathered shortly after the enactment of the federal law in 1938, and which it has used since that time in promoting the adoption of uniform legislation by the states. These proposals would add to the "Definition Section" several new definitions—"butter," "package," "nonfat dry milk," "pesticide chemical," "raw agricultural commodity" and "food additive." It would change the food adulteration section by removing the "per se" phraseology and substituting language practically identical to Section 402(a)(2) of the federal Act and which ties it in rigidly with federal tolerances as provided in Section 408(a) and 409. Some states feel that this proposed amendment eliminates any flexibility in handling problems peculiar to some of the states and renders inoperative the provision now in most state laws which reads:

> In determining the quantity of such added substance to be tolerated in or on different articles of food, the . . . [*agency or state*] shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article [food] and *the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.*

There is a feeling, too, that, as proposed, these amendments (and others dealing with drugs) would make the state laws dependent on prior action of a federal agency or of the Congress and thus make it impossible for them to act in their own behalf when necessary.

Need for More Flexible Language

We of the states do not feel that this rigidity is necessary or that making state laws dependent on federal action is desirable. While we

appreciate the time and effort that has gone into drafting these proposed amendments, we feel that more flexible language can and should be devised. This has been achieved before.

An illustration is found in Section 9 of the recommended uniform bill, which reads in part as follows:

> Whenever in the judgment of the . . . [*regulatory agency*] such action will promote honesty and fair dealing in the interest of consumers, the . . . [*regulatory agency or state government*] shall promulgate regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity, and/or reasonable standard of quality and/or fill of container. . . . The definitions and standards so promulgated shall conform so far as practicable to the definitions and standards promulgated under authority of the Federal Act.

State Standards for Foods in Absence of Federal Standards

So far as I know, definitions and standards that have been promulgated by the various states that have this provision in their laws are uniform with federal standards. But—and this is important—most of the states have promulgated standards for foods for which federal standards have not been adopted. For example, in my own State of Indiana, we have had state standards for ice cream for many years, and they have been successfully administered during those years while federal standards for ice cream have not yet been promulgated.

Another example will be found in Section 16(a) of the recommended uniform act, which reads as follows:

> No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has become effective under Section 505 of the Federal Act, or (2) when not subject to the Federal Act unless such drug has been tested and has not been found to be unsafe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the . . . [*regulatory agency*] an application setting forth (a) full reports of investigations which have been made to show whether or not such drug is safe for use; (b) a full list of the articles used as components of such drug; (c) a full statement of the composition of such drug; (d) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (e) such samples of such drug and of the articles used as components thereof as the . . . [*regulatory agency*] may require; and (f) specimens of the labeling proposed to be used for such drug.

Many other instances can be given where states have found it necessary to enact legislation or to set standards in the absence of federal legislation or standards on the same subject.

State regulatory agencies, state legislators and state attorneys feel that the prerogative of states to act for themselves when the need arises must be preserved in any amendments to state laws which seek to promote the uniformity we all agree to be desirable.

I feel certain that satisfactory language can be worked out with the assistance and cooperation of industry attorneys, especially those associated with The Food Law Institute, the Food and Drug Administration and state attorneys. As a matter of fact, the present recommended uniform bill which the Association of Food and Drug Officials of the United States has used for these many years was drafted with the able assistance of industry attorneys and representatives of the Food and Drug Administration. At the present time, the association has a committee working on the problem. It is the Committee for Revision of the Uniform Food, Drug and Cosmetic Bill and includes the director of the Division of Federal-State Relations of the United States Food and Drug Administration among its members.

I am presently a member of that committee. We solicit the cooperation and suggestions of anyone who can contribute to the solution of this problem.

Expansion of State Personnel and Facilities; Administration of New Regulations

Another serious problem that faces states in this field is the need to expand state personnel and laboratory facilities and to develop techniques and programs to administer the new regulations once they are adopted. The detection of minute traces of chemicals in foods requires the use of the latest laboratory equipment and the training of technicians in its use. Many of the states do not have these facilities or skills. They must acquire them. Field programs must be developed that will enable the state agency, for example, to acquire knowledge of what pesticide is being used on which raw agricultural crop in time to collect and submit samples to the laboratory. The laboratory, in turn, must be able to promptly analyze the sample and determine if the lot from which it came is subject to regulatory action before the food itself is distributed and consumed. Since many of the farm products are perishable, they are harvested quickly, distributed rapidly and consumed within a few days of harvest. The time element and knowledge of what pesticide has been

used is of the utmost importance if raw agricultural crops that contain excessive pesticide residues are to be removed from the market. It is not practicable to go into the market place and sample fresh fruits and vegetables for laboratory analysis without prior knowledge of what pesticide or combination of pesticides was used to treat them. About 3,000 tolerances have already been issued for some 200 pesticides on various fruit and vegetable crops. In addition, many chemicals that are used to control weeds, insects and other pests, but which may not be used on food crops, may have nevertheless contaminated them. Therefore, without some prior knowledge of what chemical has contacted the food, the laboratory will find it difficult—if not impossible—in most instances to make the necessary analysis.

Imperative Need to Accelerate Pace

It is not my intention to sound discouraging. Despite the problems enumerated in this discussion, the states are slowly but surely revising their laws and acquiring the authority to bring their regulations up-to-date. Every year, one or two enact uniform legislation or amend their laws to make them more nearly uniform with the federal Act. But there is an imperative need to accelerate the pace and to assure ourselves that the new or revised state law can keep pace with the technological developments in this highly complex field. This is of prime importance not only to the states themselves but to the Food and Drug Administration and to the interstate industries.

Illustrations

A couple of illustrations will demonstrate this need:

Without the aid and cooperation of the states, the Food and Drug Administration would have been more seriously handicapped that it was in 1959 in trying to sample and examine the thousands of shipments of cranberries, that had been distributed all over the country, to determine how many lots were contaminated with aminotriazole. Although we do not grow any cranberries in Indiana, our entire staff was immediately occupied with the task of sampling cranberries on the Indiana market. Unfortunately, our laboratory was unable to make the necessary determinations, and samples we collected had to be sent to FDA district laboratories. As samples were analyzed, district directors telephoned us the results and we, in turn, expedited the informa-

tion to merchants who were holding the sampled stocks. In a comparatively short time, we were able to get a clear picture of the condition of cranberries in Indiana and to assure the consuming public that no contaminated cranberries were being offered on the Indiana market. Many states took similar action, thus augmenting the overburdened federal field staff. Some were able to do the analytical work themselves, thus further expediting the completion of the task.

Early in 1960, an Indiana greenhouse grower was found to have treated his crop of Bibb lettuce with a fungicide for which no tolerance had been established. This Bibb lettuce was being shipped all over the country. Samples obtained in interstate commerce by the Food and Drug Administration disclosed residues of this fungicide in every instance. However, by the time laboratory work was completed, the sampled lots had been distributed and consumed. Since the federal law limits the Food and Drug Administration to articles in interstate commerce, injunctive action was the only means by which the FDA could prevent shipments. The time necessary to complete such action would render it ineffective since the contaminated crop would have been distributed. Although we do not have a provision similar to the Miller Pesticide Amendment in our state act, we were able, at the request of the Food and Drug Administration district office, to invoke a section of our law dealing with perishable foods and prohibit further shipments of Bibb lettuce until we were assured that no contamination existed. Shipments were stopped; and when the grower was unsuccessful in removing residues, he voluntarily destroyed the remainder of his crop under our supervision.

I do not believe there can be any question of the desirability of uniformity between state and federal standards in these two instances.

Conclusion

In highlighting some of these problems, I am attempting to show that the United States Food and Drug Administration needs the states if its program it to attain full effectiveness and the states need the Food and Drug Administration as a focal point or point of reference in orienting their state programs; that the states want and desire uniform standards but must be able to act each in his own behalf when the needs require it; and that industry, the consumer and the regulatory agencies can and should work together to bring about the desired result—uniformity between federal and state laws and regulations.

[The End]

Panel Discussion of Questions Submitted to the 1960 FDA–FLI Conference

A Question-and-Answer Panel Session on the Afternoon of November 29 Concluded the 1960 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc., to Discuss Food Additives, Color Additives and Other Unresolved Prob ems Under the Federal Food, Drug, and Cosmetic Act. Mr. Franklin M. Depew, the President of The Food Law Institute, Was Moderator of the Session.

MR. FRANKLIN M. DEPEW: We have now reached the final session of this joint FDA-FLI conference. I know you have found the prior discussions to be a most stimulating review of current problems relating to the food law. Our present panel will supplement these discussions by answering the questions you have presented. With these question answered, I believe this conference will have served its purpose of bringing you a full and up-to-date review of the problems in this field.

It is now my pleasure to introduce our distinguished panel. Representing the Food and Drug Administration we have Mr. William Goodrich, Assistant General Counsel of the United States Department of Health, Education, and Welfare; Mr. Winton Rankin, Assistant to the Commissioner of Food and Drugs; Mr. J. Kenneth Kirk, Assistant to the Commissioner of Food and Drugs; and Mr. Franklin D. Clark, Assistant to the Deputy Commissioner of Food and Drugs.

Representing industry and the consumer we have Dr. Bernard L. Oser, president of Food and Drug Research Laboratories, Inc.; Dr. Bruce E. Ellickson, assistant to the director of research and development division of National Dairy Products Corporation; Mrs. Ella H. McNaughton, assistant to the executive secretary, American Home Economics Asso-

ciation; Dr. Philip L. White, secretary, the Council on Foods and Nutrition, the American Medical Association; Dr. Richard S. Gordon, director of research, Agricultural Chemicals Division, Monsanto Chemical Company; and Mr. Joseph D. Becker, assistant to the director of the legal department, Allied Chemical Corporation.

The first questions are: We understand seizure actions normally are referred by FDA district offices directly to local United States Attorneys, without prior discussion with FDA in Washington. (1) Is this policy applicable to enforcement cases under the food-additives amendment? (2) If not, does due consideration in Washington of the necessity of an enforcement action include the possibility that the manufacturers involved would promptly withdraw the product from the market upon request? (3) Is there a policy regarding the cases in which publicity and press conferences will be used as an enforcement method—that is, are such methods employed against manufacturers who have never been advised or who would have no particular reason to suspect that their product might be, or might contain, an unsafe food additive.

Mr. William W. Goodrich: On the first part, there is no policy in the Food and Drug Administration of referring cases for seizure or other criminal actions directly from our field stations to the United States Attorney, with a few exceptions. We do make direct-reference seizures in, I'd say, not more than 5 per cent of our cases; over 95-plus per cent of the cases are first carried through the Bureau of Enforcement here in Washington and then through my office before they go to the United States Attorneys, so the answer to the first question is that all these cases are seen and considered here in Washington before regulatory action is taken. It is not a part of our enforcement program to ask voluntary withdrawal of violative goods from the market place. We follow a practice of proceeding against the articles in accordance with the seizure provisions of the law. There have been some recalls on new drugs, particularly where we had approved their distribution, and on some other dangerous products, but it is not a routine part of our enforcement operation to ask that the product be voluntarily withdrawn.

In the case of publicity, so far as I know there is no program of enforcement calculated to use publicity as an enforcement tool. Nonetheless, the Department of Health, Education, and Welfare is dedicated to the proposition of being forthright with the press in answering

inquiries and in making known the reasons for its administrative actions. The press conference subjects are chosen by the Secretary and others who participate in the press conferences. I do not hold them myself.

Mr. Depew: What is the status of mineral oil for use for bakery-divider or candy-equipment dressing? Can the quantity be analytically determined? Mr. Kirk, would you like to answer that question?

Mr. J. Kenneth Kirk: Mineral oil is considered to be a food additive. We have extended the effective date for that substance for use in bakeries to March 6, 1961. In the case of candy you have a different situation in that mineral oil, being a nonnutritive substance, is prohibited under the terms of Section 402(d) of the basic Food, Drug, and Cosmetic Act. The quantity of mineral oil in a food can be determined by using the AOAC method, which was originally devised by Mr. Winkler of our Division of Foods.

Mr. Depew: Dr. Gordon and some of the other industry representatives spoke against the anticancer clause. Secretary Fleming said, however, the scientists don't know how to set a safe tolerance in food for a chemical that causes cancer when fed to test animals. How does industry justify its desire to add cancer-producers to food in view of this fact? Dr. Gordon, would you like to comment on that?

Dr. Richard S. Gordon: I think I should make my position perfectly clear, as well as that of the Manufacturing Chemists Association, which is the only industry group that I can speak for. Our position is, I think, fairly simple. We feel that the problem—and my remarks yesterday, as you will recall, were addressed to the food-additives amendment—the problem isn't the direct carcinogen.

The problem is the agent which at some high level offsets some balance and will at some long term create a lesion which, in turn, may become malignant. The problem is to define what is a carcinogen or a possible carcinogen.

The position of our association is that we feel that, in terms of the food additives amendment, the recommendations of the President's special committee (the so-called Kistiakowsky Committee) should be incorporated into the food additives amendment, and this means largely a recommendation that the next Congress add the same sort of advisory panel of provisions to the food additives amendment that now is part of the new color additive amendment and that the scope of this panel

be enlarged to a somewhat greater extent than the panel that is convened under the color additive amendment. To quote Senator Hill, as I did yesterday, I think the quote that "this panel is charged with the assistance in evaluation of scientific evidence on the basis of which decisions prohibiting or permitting the use of certain compounds including certain compounds which may be considered possible carcinogens" might be made.

The point, therefore, being not that our association is for adding a carcinogen, but in the cases where one is dealing with what in many cases might even prove to be a semantic problem, to have the panel review the evidence, decide whether or not the material is a cancer-producing substance or not and, further, be able to recommend that it might be a possible cancer-producing substance at some level but at some other level it might be safe to use. Even granting the argument used by Mr. Flemming yesterday, saying that in his opinion his scientists tell him that there is no such evidence at the present time, we would rather see the concept of the panel put in the food additives amendment against the day when there might be such evidence. That answers the question, I think.

Mr. Depew: I think I'll address the next question to Mr. Rankin. Will the FDA propose legislation to the next Congress to require poisonous additives to be useful to the consumer before they can be used?

Mr. Winton B. Rankin: As Mr. Harvey mentioned yesterday, our legislative position before the next Congress will be determined by the incoming administration. We do not have a legislative position at the present time, so I am unable to say whether we would propose such legislation. As you know, the question of requiring food additives to be shown useful before they can be allowed in food was considered carefully by the two committees in Congress before the present food additives amendment was passed, and the requirement written into the law was that an additive should serve a technological purpose before it might be allowed.

Dr. Gordon: May I speak to that point? I think that this is actually quite an important point, from the point of view of us in industry. During the discussion of the food additives amendment there were people who felt that the Food and Drug Administration should perform a service analogous to the one that is performed by the USDA in certifying the usefulness of a pesticide. The actual

food additives amendment as written, though, says that the petitioner must show that the additive performs the function claimed for it, and this is a somewhat different concept.

I speak not as a lawyer but as a scientist—it is our opinion, then, that when our company says that we have an antioxidant and that's what we want to add to feed, that it is incumbent upon us to show that it is in fact an antioxidant doing this job, and FDA has to agree or disagree with this data. But it is also our opinion that it is not FDA's place to state that an antioxidant is necessary or unnecessary in feed.

Dr. Bernard L. Oser: Isn't it so, though, that the law says that this evidence for the functional—the physical or, rather, technical—effect must be shown in cases where a tolerance is required?

Mr. Rankin: That is correct, Doctor.

Mr. Depew: Mr. Harvey gave some reassurance that FDA will agree to extension of the effective date of the food additives law beyond March, 1961. Would this reassurance apply to nematocides, plant hormones, defoliants and desiccants as well?

Mr. Rankin: I believe we should recall first that Mr. Harvey's comment, which is referred to here as "reassurance," was a statement of the minimum requirements we feel should prevail before we could possibly agree to an extension of the food additives amendment. Again there has been no decision by the incoming administration as to whether it will request such legislation, and that would apply to the agricultural chemicals named as well as to food additives themselves.

Mr. Depew: I have a question here for Mr. Goodrich. A packaging material manufacturer is making and selling his product under extensions until March, 1961. He is unsure at the present what the status of the particular item will be after March 6, 1961. He is asked by his customer: May I use inventory which is purchased before March 6, 1961, after March 6? What is your opinion on this question?

Mr. Goodrich: As a strictly legal point or as a practical matter? As a lawyer, I would say the law becomes effective March 6, 1961, and the product will be illegal because adulterated while held for sale after shipment through interstate commerce, if it's used after that time.

I don't think there's any indication that the Food and Drug Administration on March 7 is going to go out and round up all the

packaging material which hasn't quite been cleared by that time. No more do I think they're going, if the law becomes fully effective on that date, to sit around for a year or two years or anything like that while everything is used up even though it has not been proved safe.

The point is that if the law becomes effective on March 6, 1961, there will undoubtedly be a planned enforcement program, and items that have not been proved safe by that time will be proceeded against on a selective basis. If the hazard from packaging material is in a high order of priority, the package will be in a high order of priority. If the hazard's in a low order, it will be down the list somewhere.

Mr. Depew: A question for Mr. Kirk: Since the Secretary may issue a regulation on his own initiative and since an omnibus petition, which pools industry practice and proprietary information on a given product is subject to possible antitrust scrutiny, would it not be better for FDA to process and pool all pertinent data from the individual companies? In this case FDA could issue a general regulation or specifications where applicable and specific regulations as they applied to individual proprietary practices.

Mr. Kirk: That's one I hadn't thought of before. The matter of antitrust action has been discussed from time to time by groups of representatives from different firms who got together to try to do a job under this food additives amendment. I got the impression (not as a lawyer) that much of the concern was more apparent than real. Now this matter of taking a whole bunch of petitions and pooling them leads me to wonder just when you would stop, when you would decide you had all you were going to get.

But as a practical matter, supposing you do have two or three petitions before you on essentially the same subject and you may find that for a large part they more or less duplicate one another. Then they change in some specification or other feature. Why shouldn't we go ahead and say: "Well, we will issue a regulation covering all three of these because they can fall into the framework of the single set of specifications." We haven't run into that yet to my knowledge. There's no reason why we couldn't.

Mr. Depew: Mr. Becker, would you like to comment at all on that question?

Mr. Joseph D. Becker: I haven't a comment, but another question for FDA. Those comments figured in my mind. In the last

session of Congress a bill was enacted authorizing the Secretary of the Interior to get trade associations to cooperate in doing research of a scientific kind on call. The thought occurred to me, and I wonder, whether FDA has given any thought to the encouragement of toxicological research among interested producers in a cooperative way in a form which would assure that they had no antitrust problems.

Mr. Kirk: Well, hasn't that been done? It was my understanding that we have received toxicological information which was provided by the combined efforts of a number of firms hiring a particular toxicologist or group of laboratories to do the work for them.

Mr. Becker: But not without trepidation about the antitrust laws.

Mr. Kirk: That I can't speak for.

Dr. Gordon: I think we might add that, in the deliberations that we have in the Food Additives Committee of the Manufacturing Chemists' Association, we have agreed that we will not as an association file any petitions for three, eight or ten of our member companies. We will give them all the help that we can as an association, but they will have to act either in concert or as individuals.

Mr. Depew: A question for Mr. Goodrich: The listing of components on ingredient labels should be put in order of amounts. How is this determined—on a dry basis or on an as-is basis?

Mr. Goodrich: This is the kind of a labeling question that I very seldom see, as a lawyer, and haven't any real opinion on it that's worth very much. I think Mr. Kirk's opinion would be better than mine. I can say that the order of listing of ingredients is provided for by our regulations in terms of order of importance in your mixture and this is an interpretative regulation arising under our false and misleading labeling provision. Whether it's on a dry basis or an as-is basis, I'll have to ask Mr. Kirk.

Mr. Kirk: Unless you have a very unusual product, I would say on an as-is basis because that's the food you're selling and that's what you're talking about. Dry basis usually just gets into your analytical data and puts questions of how to go about setting standards, where you've got to be sure everything's on the same basis.

Mr. Depew: A question for Mrs. McNaughton: In his fine talk Mr. Sullivan remarked that consumers failed to attend public discussions on food problems. Is this because the press does not inform

them of such meetings? For instance, I saw no announcement of this vitally important conference in our local newspapers. Is this the fault of the press or of public relations of The Food Law Institute or the Food and Drug Administration?

Mrs. Ella H. McNaughton: Well, I think the consumer is interested in problems that are of her concern. I think she wants to know about these. I think there are certain meetings which technically she might not find too much interest in. I think the press covers topics pretty well. I think they bring them to the attention of the consumer. We had several very vital consumer articles in the papers the last few weeks. I think The Food Law Institute is doing a fine job. I think that, really, the consumers who want information find the places where they can go to get it and they are represented there at the time that the meeting goes on.

Mr. Depew: In further answer to that question, I would like to say that The Food Law Institute did release a press notice about this meeting and I think the Food and Drug Administration did also.

Dr. Gordon: Can I make an official comment on this?

Mr. Depew: Surely.

Dr. Gordon: It's been one of the interesting things to us in the Manufacturing Chemists' Association that nearly everybody tells us the kind of thing Dr. Emil M. Mrak said this morning and yet most of the chemical companies, for example, do not reach the consumers. We sell to food companies or processors, and I thought it might be worthwhile to tell you what we are doing this year.

We have made quite a substantial appropriation from our trade association budget to concentrate on giving talks to the teachers of home economics of departments of nutrition in high schools and in colleges. As they say in the scientific meetings, "just by chance I brought a few slides"—actually, I brought a list of what we've mailed out. The mailing list is something like 45,000 home economists, teachers of domestic science, dieticians, and so on.

We first sent out the FDA food additives booklet and its leaflet *Food Facts Versus Food Fallacies*. We got an amazingly warm response to this, although the FDA itself has not sent this booklet to this group of people, which surprised us. We sent out the Kistiakowsky report and then we sent out the Supermarket Institute papers called "The

Good in Your Food" and then we sent out a booklet which is called *Open Door to Plenty.*

Now besides that, in looking at the need, we are in the process of writing a booklet called *The Basis*—a basic source booklet on food additives—which is in the process of being published and which will be sent to this same key list. This will be a rather fact-full description of all the chemicals used in foods. We are also making a user's guide in it—how some of these chemicals that may not be covered in this first booklet are used.

In other words, as a trade association does not deal with the consumer we have decided to concentrate on the educators who are dealing with this problem at a rather local, specific level and we think that we can be of service here.

Mr. Depew: Another question for Mr. Goodrich: In an article concerning empty containers in the FOOD DRUG COSMETIC LAW JOURNAL for October, 1960, John G. Kuniholm concludes that all "food additives" within the meaning of Section 201(s) are not "food" within the meaning of Section 201(f). Does FDA agree with this?

Mr. Goodrich: This is an old question we threshed out last year down here about whether a tin can that had a poisonous food additive in it was to be subject to seizure. I ventured the opinion at that time that there was an ample authority to deal with the problem. John Kuniholm made a speech at the American Bar Association disagreeing with me on half of my problem—half of my rationale—and said he would restudy the rest of it.

As far as I'm concerned, it is true that "food additives" were not specifically made "food" by definition when the food additives amendment was passed. The Congress' explanation for that was: "It was unnecessary to do so." All this is discussed in Mr. Kuniholm's paper and I believe he did give our answers. But—to restate them—if any container has a poisonous substance in it that is reasonably expected to migrate to food and the container is being shipped to, or is in the possession of, a food processor, we would not hesitate to attempt to take regulatory action to prevent its use before food was packaged in it, thereby rendering the food adulterated. We think the law is ample to cover that point.

Mr. Depew: I have another question—I think for you, Mr. Goodrich. A liquid being marketed under an effective new-drug applica-

tion contains a trace of FD&C Red No. 1. May the Red No. 1 be dropped without a formal supplement?

Mr. Goodrich: Mr. Rankin tells me you have to have a formal supplement. My comment would be: It had better be dropped pretty quick.

Mr. Depew: Recently there have been press reports concerning one packaging industry's petition which in effect requests the issuance of a regulation on the basis of the fact that all components used in the industry's products are nonmigrating, prior-sanctioned, GRAS (generally recognized as safe) or covered by other regulations.

(1) How does FDA view this approach to petition filing and regulation issuance as a general concept which may be employed by other industries or other individual petitioners?

(2) Assuming that all the chemical components of the packaging material are nonmigrating, prior-sanctioned, GRAS, or covered by other regulations, is it sufficient that a petition for regulation simply states that fact with no additional data being submitted or required? Mr. Kirk?

Mr. Kirk: Well, that's a big one. I'm not sure I understand the question fully. Certainly no regulation is going to issue for a product the components of which are not fully known to us and about which we do not have full information.

Then there is the question of whether or not all of these GRAS and prior-sanctioned items remain as such or whether they react with each other and perhaps form some new compound or compounds which themselves could be food additives. I'm afraid this is so general I can't give you a yes-or-no answer. You'd need all the facts.

Mr. Depew: Thank you.

Another short question for Mr. Goodrich: Are labels that are placed directly on meat in a retail store subject to federal food-and-drug action?

Mr. Goodrich: Since this meat is outside an inspected establishment the Meat Inspection Act does not apply. As I understand the question, the Food, Drug, and Cosmetic Act would apply to the extent that the product—a meat food product which becomes misbranded while it is held for sale after shipment in interstate commerce—is subject to action under the Act.

Mr. Depew: Another short one for you: What happens to products packed under standards of identity when present optional ingredients may impart a color, but color is not provided for in the standards?

Mr. Goodrich: On this I refer you to our recently drafted color regulations which are to be published in the *Federal Register* within a few days. In these regulations, our interpretation of what is a color additive is that food ingredients which carry their natural color into a food mixture—that is, orange juice or chocolate, or cherries, or something of that kind—are not believed to be color additives, and I think that would answer the question.

We are not taking the position that the color from a food ingredient is a color additive unless it is deliberately used for that purpose. For example, beet juice used in making pink lemonade is a color additive. Orange juice in a mixed food is not a color additive. These regulations will be subject to comment. We hope we'll get a lot of comments from you, and on this point we will appreciate any suggestions that can be made.

Mr. Depew: I have a short but difficult question: This morning Dr. King said that several nutrients are carcinogens. What carcinogens are essential in human nutrition?

Dr. Oser: As I indicated yesterday, a lot depends on your definitions. If the definition of a carcinogen is so broad as to include the substances that are remotely, rather than directly, related to the carcinogenetic process, any substance, for example, that would produce oxylate deposition in the bladder might be considered to be carcinogenetic. This would include foods, of course, containing oxalic acid; it would include foods which contain nutrients which metabolize to oxalic acid.

Ascorbic acid is a case in point. Other nutrients were mentioned by Dr. King this morning—selenium and chromium. It's true that these have not yet been established to be essential in human nutrition, although they have been established as essential in certain types of animal nutrition. These are the only ones that I can cite offhand.

I wouldn't call heated fat or roast meat essential nutrients specifically but there is evidence that heating and smoking produces carcinogenetic substances, so that whereas these are not specifically nutrients, they are components of our natural diet. A well-known and unquestionable carcinogen, benzopyrene, has been identified in roasted coffee and in smoked bacon. I think many of our smoked foods con-

tain carcinogens if they were isolated and identified in concentrated form.

Dr. Gordon: If you don't want to take a chance, you can give up food. (Laughter)

Mr. Depew: What is FDA's attitude toward, and its estimate of the seriousness of, the problem of drifting chemicals or pesticides which may result in unauthorized residues on agricultural commodities?

If FDA considers this a serious and present problem, what guidance can FDA offer to the processor who may be unaware of potential unauthorized residues? Mr. Rankin?

Mr. Rankin: We are aware that pesticides being applied along the borders of one field may drift and contaminate an adjoining field that was not supposed to be sprayed or dusted. Whether this is a serious situation depends, of course, upon whether the drift leaves unauthorized residues on the second field. We have encountered one or two instances in which illegal merchandise resulted from what the grower told us was a drift problem, and Dr. Mrak called our attention this morning to the awareness of the California authorities in this same area.

Our recommendations as to the steps a processor may take to guard against such problems would be that the processor, in line with what we understand are accepted procedures in canneries and freezing establishments today, have his field men in the field on the alert to determine not only that pesticides are used on the crops he has contracted for, in accordance with contract specifications (which will guarantee safe legal residues) but also that these field men be alert for possible abuses such as drift. While we are not involved, there is also the defense that the innocent grower has, through civil suit, against the man who sprays or dusts his crop when he didn't want it sprayed or dusted.

Mr. Depew: How was it legally permissible for FDA to give the Bronk Committee, composed as it was of members of the National Academy of Sciences-National Research Council, access to new-drug applications in view of the provisions of Section 301(j) giving protection to trade secrets revealed under Sections 404, 409, 505, 506, 507, 704 or 706 of the Act? Mr. Rankin?

Mr. Rankin: I presume that the Bronk Committee referred to is the committee of scientific experts under the chairmanship of Dr.

Miller, appointed by Secretary Flemming to look into the decisions that we have made in the new-drug and antibiotic fields. The members of that committee, as well as the secretariat, were appointed consultants to the Food and Drug Administration. They took the oath of office of a government employee. They were subject to the same penalties that full-time members of the Food and Drug Administration are for unauthorized disclosure of trade secrets. They were, for the time they were working on these files, members of the government.

Mr. Depew: Mr. Becker, a question for you. What is the best way for manufacturers to keep up with the various laws and activities —for example, the actions on the standards of identity for frozen desserts?

Mr. Becker: Well, my way is by getting on the FDA mailing list. I don't know of any other, better way.

Mr. Depew: Dr. White, does the public get a false impression of protection from the Miller Pesticides Act? The cranberry incident illustrates that the Department of Agriculture can certify dangerous economic poisons before FDA has developed an adequate method of detecting residues of same.

Dr. Philip L. White: Well, it's certainly not possible for me to speak for the consumers on this question. I don't think that the public gets a false impression of protection from the Miller Pesticides Act so long as the provisions of the act are followed and so long as the users of the pesticides follow label instructions. I think the difficulty comes when we have so many agencies that are conflicting with each other. As I recall, it was about that time that the USDA wanted to take over the Food and Drug Administration and this must have caused great consternation to the consuming public.

I don't think that the public is aware of the provisions of the Miller Act, or the Miller Amendment, nor do I think that they are well aware of the significance of the quantitative and the qualitative aspects of determination of pesticides. I don't think they know, for example, that there are at least two steps in determining tolerances for these residues. I think that the public is taking each of these experiences as a brand-new experience.

Mr. Depew: Thank you. A question for Mr. Goodrich: The tentative regulations for the enforcement of the anticancer clause use

the phrase: "if studies suggest the possibility that a substance may be a carcinogen." Such a phrasing appears to go beyond the requirements of the color additives law.

In legal matters of this kind, tradition has established that the evidence must show guilt beyond a reasonable doubt before guilt is established. Would it not therefore be adequate to use either of the two following phrases: "indicates the possibility" or "suggests the probability"? These alternatives show that a reasoning process was involved.

Mr. Goodrich: I recommend that whoever sent this question in get the proposed regulation out again and reread it. What it says is that at any time we have evidence which suggests the possibility that the product might be a carcinogen, the Commissioner shall proceed to determine whether (and I quote) "based on the best judgment of appropriately qualified scientists, cancer has been induced and the color additive and any of its components or impurities was a causative factor."

Now this is written exactly in terms to say that whenever the question is raised, the Commissioner is directed to bring to bear on it the best scientific judgment there is. I don't know of any better way to say it and if you read the whole sentence I don't think there's any basis for suggesting the possibility here that we've misread the law.

Mr. Depew: We buy frozen fruits and juices for manufacturing preserves and jellies. How do we assure that we are complying with the law as to pesticide residues being present? Dr. Ellickson, would you like to comment on that?

Dr. Bruce E. Ellickson: The best suggestion I have there is for you to consult the supplier from whom you buy the frozen juices; find out what his source is and have him give you assurance that he has control measures in practice to see that the pesticides are kept out of the products he sells you. This is a very difficult question to answer because you may find your supplier doesn't know anything about pesticides to begin with.

Mr. Depew: Another question for Mr. Goodrich: Previous conference questions and answers state that FDA believes:

(1) Empty cans and, presumably, other forms of empty food packages are not foods, even though produced for, and intended to be used for, food packaging.

(2) FDA has the right to inspect a plant where cans are manufactured and, presumably, plants where glass jars, cellophane, and other forms of food packaging are manufactured.

Could you explain the statutory basis for the authority to inspect factories which produce food-packaging material? These actions refer only to plants performing certain activities relating to foods (or drugs or cosmetics) as we read them.

Mr. Goodrich: Someone's trying to get me to make the foolish statement that a can is a food and I'm not going to do it. (Laughter)

In terms of threshing this old question, I went over it a few minutes ago. The question of inspecting these places has not come up. As you know, our inspection authority is supported by a criminal statute and of course is likely to be strictly construed. I must say, however, that if anyone will look at the polypropylene food additive regulation he'll see that it is established in terms of what was used in preparing that substance.

As a practical matter, we're not going to be able to issue regulations, apparently, for some packaging material without doing it on the basis of specifications for the packaging material. In order to make those regulations effective there will have to be an adequate inspection power. I don't anticipate any difficulty on this nor am I here suggesting that when we bring our first criminal case to get a reliable interpretation of the factory inspection authority, we go into some can company to start. The statutory basis for the authority to inspect would have to be that the food additive is a food because it is intended for use which results in its becoming a component of food. Where there's an adequate public-health problem justifying the inspection, I have no doubt that we are authorized to make an adequate inspection there.

Mr. Depew: I would like some more information on the labeling of detergents under the Hazardous Substances Labeling Act. Mr. Rankin said some detergents are irritants. My question: What test does FDA use to determine whether a detergent is irritant? Was Mr. Rankin referring only to synthetic detergents or did he intend to include ordinary soaps in his statement? Mr. Rankin?

Mr. Rankin: The information that we will rely upon initially as we draft regulations under the Hazardous Substances Labeling Act is largely information that has developed from actual use of products.

It is well recognized that some of the synthetic detergents do irritate people that use them. I'm acquainted with a number of women—and I expect each of you is also acquainted with a number of women—who cannot use certain synthetic detergents in the dishwater without putting rubber gloves on. If they do, they get a terrific rash. Some of the detergents used in automatic washing machines are quite irritant. I did not intend to exclude all soaps because we recognize that an alkaline soap likewise may be an irritant.

We have not yet arrived at an animal test, so far as I know, that gives the same answer that the human test I've just mentioned gives with respect to irritants. Our Division of Pharmacology is studying the possibility of using rabbit skins as a test medium. Some members of industry are studying the possibility of using the rat skin or the mouse skin, and we would hope that suitable animal testing procedures can be developed in the near future.

Mr. Depew: Another question for you, Mr. Rankin: When will FDA issue the first regulations under the Federal Hazardous Substances Labeling Law? Will they be discussed with the interested members of industry before they are issued?

Mr. Rankin: We are unable to state a definite date by which time the first regulations under this law will be issued. We hope it will be in the near future. We are in the process now of discussing proposed regulations with some of the interesed industry associations.

We understand that at least one association is drafting proposed language to bring down and discuss with us and that one or two of the other associations are considering the drafting of proposed language. We will welcome such recommendations and discussions before publication of our regulations, but we cannot, of course, commit ourselves to withhold publication of proposed regulations when they are drafted.

Mr. Depew: A question for Mr. Kirk: Section 121.3(c) and (d) of FDA regulations indicates that the Commissioner on written request will advise interested persons if a certain use of a specific product has been sanctioned or approved and if, in the opinion of the Commissioner, the substance is a food additive.

(1) Paragraph (c) refers specifically to sanctions and approvals. Will the Commissioner express an opinion as to the safety of a certain

product for a specific use if such use by other parties is by virtue of a letter of opinion rather than by either a sanction or approval?

(2) In the case of either sanctions or approvals or an opinion that a product is not an additive, will the Commissioner upon written request by an interested party indicate that the same, or a similar, product may be used for the purposes specified if the applicant describes the product and its use but does not identify the product as that of the other party receiving such previous approval or name such other party or furnish FDA a letter of authority from such other party to use the data previously furnished by it to FDA?

That's a little bit complicated. (Laughter)

Mr. Kirk: Let me try it. As to the first part, by far the great majority of your "sanctions or approvals" prior to the enactment of the food additives amendment were by letter of opinion, so to speak. Except for chemicals listed in the standards, most of the people got a letter saying: "We've looked over your material and we are satisfied that this is O. K. for such and such a use." So the fact that it was by letter of opinion doesn't really make any difference.

As to the second part, if someone writes to us and says: "here is X product of ours; please advise whether this has a prior sanction." if we find that it has been "prior sanctioned" for a specific use we will so advise that inquirer and we won't require any authority from the man who got the original prior sanction.

However, it must be kept in mind that when we gave these prior sanctions over the years, they were not given with the thought in mind that they would be a basis for a "grandfather clause" in this food additives amendment. Therefore, we didn't set up a filing system which would guarantee that having just the name of the product or just the formula would give us the basis for going back and finding that sanction. Sometimes we have to say: "No, we don't find a sanction." Then we get a letter saying: "But you did give a letter of approval to So-and-So back in 1942." We go to So-and-So's file and we find it. So there will be some cases where we may need the name of the firm to whom the original sanction was given before we can really be sure that we gave it.

Mr. Depew: Another, somewhat similar, question: Prior sanction statements from FDA often consist of letters stating: "No objection to the use of the additive in food." Out of an abundance of caution,

such letters have sometimes included a warning consisting of the obvious legal fact that the statement of "no objection" was not to be considered as applicable to standardized foods.

(1) Does the FDA consider this as being a limitation upon the prior sanction such that the additive will be held to be a "food additive" under the food additives amendment when one is seeking an amendment of a particular standard to permit the optional incorporation of that additive? In other words, would amendment of the standard have to be preceded by a petition under 21 CFR 121.51?

(2) If the answer to the above question is in the affirmative, does it make any difference if the warning statement in the prior sanction was omitted—that is, must all "prior sanctioned" materials be considered as "food additives" in a standardized food unless the standard already permits their incorporation?

Mr. Kirk: With respect to the first question, we've got to start with the premise that any sanction we gave over the years must be strictly construed. You read it for what it says and then don't say: "Now, well, of course, let's forget the last few words," and so forth. If the sanction letter did not give approval for a standardized food, we can't say that there is a prior sanction for that particular use for that particular product.

Now coming to the second part of the question, however—must all "prior sanctioned" materials be considered "food additives" in standardized foods?—let's evaluate the "prior sanctioned" product. Who knows? Perhaps it may be found to be a generally-recognized-as-safe item now, because many of these prior sanctions go back a good many years.

Even if you do have a food additives question here, however, I hope you'll all note the changes we've been able to make in the handling of food additives and food standards provisions during the past four or five months. We think we've got a streamlined way of handling these and there shouldn't be too much concern about that feature.

Mr. Depew: I have a few questions for Mrs. McNaughton:

Most foreign countries do not require that ingredients be set forth on the label. Now that we can rely on the safety of ingredients being established under the food and color additives amendments, I can see

no need for this ingredient statement. Of what value is it to the consumer?

Mrs. McNaughton: Well, let's take the foreign countries first. It's been our experience in the American Home Economics Association that we have had visitors from many foreign countries who come to us and ask us how we reach the consumer. They are very interested in what we have done; they are very interested in how we reach the consumer; and they are very interested in going back to their countries and doing something else for their consumers. My point there would be that I believe that in foreign countries they are trying to get more information to the consumer.

Now, let's see, the second part of that question was about consumer labeling, wasn't it?

Mr. Depew: Yes.

Mrs. McNaughton: Let's say it this way: The Commissioner has said from time to time—and again and again—that the consumer has a right to know what is in her food. I believe that the producer has a very fine opportunity to communicate with the consumer by adding information to his label.

I believe that we need more information given to the consumer. Many of them are interested in special diets. Many of them want to know whether certain ingredients are in a product. Many of them are interested in the nutritive value of what they buy and if the label gives us this information we can select—we can choose what we want.

I believe there is also a responsibility there of educating the consumer—give her more information, not less. Let her know that there should be some accuracy to the information that is given her. Encourage her to read the label. I believe we need, as far as our food is concerned, to know what we are eating and I believe the producer has an opportunity to give us this informtaion.

Mr. Depew: A somewhat similar question: I see labels reading in part: "sodium propionate added to retard spoilage," "mono and di-glycerides—harmless softener," "butylated hydroxy toluene (a preservative)." I am perforce becoming acquainted with these chemical terms but wonder about their value to the consumer. They clutter up the label and take space which might be used for other information. Do you agree? (Laughter)

Mrs. McNaughton: Well, what other information would the consumer want than the ingredients that are in the package? I believe that that is what she's looking for. I think that here there is, perhaps, something that has been brought out time and time again. I think it was brought out yesterday that labeling was very important; that you were interested in having labels that were readable; that you were interested in having the kinds of labels that were informative.

I believe that there is a sort of a standardized nomenclature which perhaps we need to adopt as far as the consumer is concerned. Some of the names undoubtedly will not mean much to her because she has never come into contact with the product. She doesn't know much about the ingredients. But the very fact that that ingredient is on the label gives her some assurance that it's all right for her to have. Otherwise it wouldn't be there. I think it is in her protection or to her protection and I think it is in the interests of the consumer to have functional and common names on the label for the consumer to read.

Dr. Gordon: Could I make a comment? I think that this again speaks to the point that Dr. Mrak made this morning—that we've had, for too long, too little information reach the consumer and, of course, this is the reason that the Manufacturing Chemists' Association, in cooperation wtih the Nutrition Foundation, is trying to reach the teachers actually in the high schools and the colleges who teach home economics and dietetics and nutrition, and so on, so that we will have more and better-informed consumers so that they will recognize that these materials are there for a purpose and that they are not zero or minus, but that they're there to improve the food.

Mr. Depew: Most labels do not show the amount of fat, carbohydrates, proteins, etc., nor the caloric value of a given amount of food. Do you think this information should be given in the interest of adequately informing the consumer?

Mrs. McNaughton: That's a very interesting question. Some packaged foods do give caloric content and they also give the percentage of proteins, carbohydrates and fat. However, I believe that, generally speaking, many of the producers would find it very difficult to put the composition of the food on the outside of the package. I think it would create a real problem for them.

I think it's interesting to note that a consumer's survey has been made on new packaging that we want. One of the questions that was

asked was: "Information as to calories and vitamin content on labels of all food: does the homemaker want them or does she not want them?" And the homemaker decided—80 per cent of the homemakers decided it was a good idea. So the homemaker is interested.

Now that should be a pretty good indication for the purposes of the manufacturers who are working on low-calorie food or it should also be a rather good indication for the manufacturers who are trying to put out very nutritious foods for the buyer, the consumer who wants to go to the store and get the most for her money. I think it shows the consumer interest. I think in some instances it is not too practical.

Mr. Depew: Thank you.

A question for Mr. Kirk: What is the status of new products for use in food-packaging applications composed of an "approved" major component in combination with one or more minor components covered by extensions for their use until March 6, 1961?

Assuming no chemical interaction, can such products be considered to be covered by extensions until March 6, 1961?

What is the proper method for obtaining an opinion or approval for their use?

How long a period can reasonably be expected to elapse before such an opinion can be obtained?

Mr. Kirk: With respect to the first part, we need more information to be responsive. For example, we need to know whether the components react with each other to produce a new substance and, if so, what the substance is.

The method for obtaining an opinion is to ask us. The method for obtaining an approval for a substance—a food additive—which does not have a prior sanction and which is not GRAS is via the petition route.

How long a period can reasonably be expected to elapse? If we get an inquiry we will process it as fast as we can, consistent with the other problems which are facing our people. Now, if you have a technical question which has to be reviewed by the folks in the Division of Food or the Division of Pharmacology, you've got to keep in mind that they have a great many such problems facing them not only in the form of letters, but also in the review of petitions. They are, I can assure you, doing the very best that they can. I wouldn't want

to give you a date. Of course, if it's a petition, we have the statutory time of 90 days or extension, if necessary, to a second 90. There, again, we want to do it as fast and as well as we can.

Mr. Depew: We still have quite a number of questions; I suggest we try to make our answers as brief as possible and see if we can't get through them. Thank you, Mr. Kirk. I have another question for you. What is the differentiation between products which are used as food packages, those used in food processing and those classified as housewares? What is the status of each with respect to the food additives amendment?

Mr. Kirk: Well, the food-packaging items and the food-processing items would be essentially in the same category where there is migration from the package or the equipment to the food.

However, when you come to housewares such as plastic dishes, for example, which are solely for use in the home, and that sort of material, the food additives amendment does not apply. Keep in mind, however, that these materials may be subject to the amendment when used for other purposes. For example, a paper cup that you may use at home would not necessarily be covered by the food additives amendment whereas the same cup used commercially would be; of course, regardless of where it's used, it should be safe.

Mr. Depew: What is the proper differentiation between the jurisdiction of the Food and Drug Administration and the Department of Agriculture in food processing and packaging? Are extensions granted certain products by the Food and Drug Administration honored by the Department of Agriculture and, if not, can the Department of Agriculture grant extensions?

Mr. Kirk: We have the authority to grant extensions under the food additives amendment; whether the Department of Agriculture—the Meat Inspection Act or the Poultry Products Inspection Act—elects to permit the use of such a substance as may be extended, is entirely up to them, because they are putting their name on the finished product. Agriculture does not have the authority to grant extensions under the food additives amendment.

Mr. Depew: Under Section 409(i) of the food additives amendment of 1958, it is provided:

> . . . the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing

such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

The question I would like discussed is concerned with what does the Secretary or the FDA contemplate under this provision of the law and how does one proceed to conduct the necessary field testing to justify the complete toxicological studies, assuming preliminary indications of safety, to provide the proof of safety required for the filing of petitions so that the introduction of new food ingredients will not be stifled?

Mr. Kirk: Quickly, the answer to that is in Regulation 121.75, which deals with shipments of food additives for investigational use.

Mr. Depew: It appears that the FDA has received many more petitions than it can possibly handle before March 6, 1961. Furthermore, it is well known that some companies are performing tests which cannot be completed before March 6, 1961. Will the Administration request from Congress authorization to grant further extensions beyond March 6, 1961? If so, will you please detail the request to Congress which is contemplated by the Administration?

Mr. Kirk: I think the best I can do is refer to what I quoted Mr. Harvey as saying and what he said himself yesterday morning.

Mr. Depew: A number of so-called "blanket petitions" have been submitted to the FDA covering incidental additives which may migrate from various packaging materials and processing equipment. At the time of writing this question, at least one of them has been officially filed. While at one time certain FDA officials encouraged the blanket approach to this type of problem, it has been rumored that there has been a change of policy. Please clarify current policy.

Mr. Kirk: I think perhaps there's some confusion here, maybe arising out of the use of the term "blanket" or as some people have said, "omnibus." This has got to be an individual thing as far as consideration of hazard is concerned but certainly there has been no change in our policy that a petition such as the one submitted by the Can Manufacturers' Institute is proper and, as I mentioned yesterday, we are currently filing a comparable one submitted by the Adhesive Manufacturers' Association. No change in our policy.

Mr. Depew: How far may prior sanctions on a package be extended to other packages; for example, we understand that the biscuit dough canister consisting of a spirally wound aluminum foil-lined

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paper tube with metal ends has been the subject of a prior sanction or letter of "no objection" from the FDA. Does this mean that similar canisters made by other manufacturers are also under this prior sanction? Would this prior sanction apply to other acidic foods such as frozen fruit juices?

Mr. Kirk: The prior sanction given to one manufacturer would apply to the identical article made for the same purpose by another or as many as there happen to be. However, a prior sanction which is granted for biscuit dough certainly would not be regarded as extending to acidic products where you might have an entirely different extraction problem.

Mr. Depew: In many cases and, in particular, in linings for food containers one is permitted to provide materials for contact with food on the basis that the ingredients are listed in the *Federal Registrar* as being on extension until March 6, 1961. This date is just a little over three months away, and in the meantime the food-packaging industry is preparing containers which may not be used until after March 6. How can the container manufacturer assure the food packer that those containers now being manufactured under the extension provision will be acceptable to FDA after March 6, 1961? I believe it is essentially the same question that Mr. Goodrich answered.

Mr. Goodrich: That's correct.

Mr. Depew: The food-packaging industry requires written evidence that a material used by them is acceptable under the provisions of the food additive amendment. The staff at FDA is not sufficient to provide these letters and most often does not have the information upon which to base a ruling. How can a food packer be assured that the materials he is using are acceptable to FDA? Who is legally responsible—the packer, the container manufacturer, the coating manufacturer or the raw material supplier?

Mr. Kirk: Of course, the easiest way to handle that would be to say if the material is covered by a formal regulation then he and everyone can take a look at it and see whether it complies. As far as who is responsible, I think you have to take into consideration all of the facts in any particular case and, perhaps, in some instances, everyone that you name would be responsible. Do you agree with that, Mr. Goodrich?

Mr. Goodrich: Yes.

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Mr. Depew: Will there be any attempts by FDA to insure properly qualified, objective public disclosure of official information and to educate the science writers, etc., in objective interpretation to the public without the use of sensationalism (also called "reader interest")? Mr. Clark, will you make comments on that?

Mr. Franklin D. Clark: Well, historically the Food and Drug Administration has always believed in an informed consumer and informed industry. We have been and are using, and will continue to use, the proper methods to provide as much information as we possibly can.

Mr. Depew: What assurance does the consumer have that food or food ingredients containing direct or indirect food additives will be labeled so that such foods can be avoided if desired?

(1) Will trace level additives be labeled? For example, will spice extractives containing a residual solvent with a tolerance of ten parts per million be so labeled?

(2) If trace level additives are required to be labeled, is there a lower limit for such requirement?

(3) Has there been any disclosure so far that a food additive having an approved tolerance and so labeled in a given food, is being used in another food within the approved tolerance level without labeling?

(4) Does the FDA have a program in effect to uncover the possible violation referred to in (c)? Mr. Kirk?

Mr. Kirk: First, this matter of labeling for ingredients would be covered by the specific terms of Section 403(i)(2) and (g) of the basic law. Certainly if it is not a standardized food, a direct additive would have to be declared by its common or usual name. If it's a standardized food, then the terms of the standard would prevail. In general we would *not* regard this ten-part-per-million residual of a solvent from the preparation of a spice extract as a substance calling for declaration under Section 403(i)(2).

However, I hasten to say: Let's not carry that too far. There may be some instances where the residual material or the incidental material, if you will, would have a definite effect or bearing on the finished food in which the particular ingredient is being used, and then we would have to consider not only the question of whether or not it is proper for that food, but also whether a label declaration is called for.

The next part—has there been any disclosure?—I don't know of any.

Do we have a program in effect? Yes. We do have our inspectors making factory inspections regularly and as a part of their work they are checking on this food additives matter just as they do other possible violations of the statutes.

Mr. Depew: What is the current status of ethyl alcohol as a food additive?

Mr. Kirk: We regard it as generally recognized as safe.

Mr. Depew: Does the FDA have a project under way or planned to establish whether a considered selection of widely used food processing operations employing physical and/or chemical agents now considered to be GRAS are in fact safe as judged by comprehensive feeding tests?

Mr. Kirk: I don't know of any except perhaps methyl salicylate, which was on our original GRAS list and on which, last November, we decided to defer final comment until Dr. Lehman's work on feeding that substance had been completed.

Mr. Depew: Would it not be more accurate and consistent if FDA tolerances were expressed as parts per million to the dry matter content of a food rather than on the "as is" basis?

Mr. Kirk: Well, we've considered that from the same standpoint, essentially, as we did this matter of how you determine the order in which you list ingredients. After all, here is a specific food and we are setting a limit for that particular article. There may well be some instances where this dry basis would be a proper determination, but if you don't have to dry the thing to find out, let's not put one more step into the chemical determination of the additive.

Mr. Depew: Another question for Mr. Clark: How can FDA reconcile an item listed as GRAS under the food additives law being provisionally listed under the color additive law until its safety is established?

Mr. Clark: Well, under the color additive amendments there is no provision for a "generally recognized as safe" list. Until final promulgation of the general enforcement and administrative regulations there would be no way to list a color additive under anything but the provisional list.

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Mr. Depew: For Mr. Kirk again: Substances on the GRAS list must be of appropriate food grade and be prepared and handled as a food ingredient. The regulations provide that upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food. However, is it not possible to formulate specifications which, if met, would satisfy the "food grade" test for the general use stated in the GRAS list?

For instance, is it not possible to formulate specifications for substances such as calcium carbonate, calcium chloride, calcium citrate, and calcium gluconate for use as buffers and neutralizing agents which would meet the "food grade" test without regard to the particular product in which the substance is so used?

Mr. Kirk: Well, I think it would be possible to do that. As a matter of fact, various manufacturers have already done so and I would guess that most manufacturers of those substances have a "food grade" which, if we were asked about it, we'd say: "Certainly, we agree."

On the other hand, keep in mind that this GRAS list to which reference was made covered 178 different items and, of course, there have been additional GRAS lists since then. If we had tried to work out a specification for each of those items, you wouldn't have that GRAS list yet. There is a growing desire for a codex of these various items. Right now, the Food and Drug Administration just *can't* do it, although we are still willing to comment as offered in that notice.

Mr. Depew: A question for Mr. Goodrich: The cranberry episode has been associated with the food additives amendment. Wasn't it really an infraction of the Miller—or pesticide—Amendment?

Mr. Goodrich: Insofar as the seizures were concerned with fresh berries, it was a pesticide-chemical case; insofar as they were concerned with canned products, it came under the food additives amendment. There were few cases on canned berries, but mostly on fresh berries.

Mr. Depew: A question for Mr. Rankin: Among the recommendations of the President's Science Advisory Committee Panel on Food Additives was the proposal that the Secretary of Health, Education, and Welfare appoint a board to advise him in evaluating the evidence relative to potential carcinogenicity. Has such a board been appointed

and has it considered the evidence with respect to the food and color additives which FDA has interpreted as carcinogenic?

What is the present status of organic arsenicals, stilbestrol, and polyoxyethylene monostearate insofar as alleged or suspected carcinogenicity is concerned?

Mr. Rankin: The Secretary has appointed a committee to consider the evidence on one chemical. The committee report has not been released, but our Department is following the suggestion made by the Kistiakowsky Committee in that regard. The present status of the organic arsenicals (I presume that refers to the use of organic arsenicals in animal feeding) is that those materials which were approved or sanctioned by the new-drug-application route or by the antibiotic-application route before the food additives amendment became law may still be used by the firms who have sanctions. They may not be used by other firms until these other firms have effective new-drug-applications or effective antibiotic applications.

Some question has been raised about the organic arsenicals because it is known that some inorganic forms of arsenic, specifically sodium or potassium arsenite can cause cancer. We believe that before the Food and Drug Administration could approve a petition for an organic arsenical, saying that it is safe, it would be necessary to conduct further testing or at least a very complete review of the available literature to determine whether those materials are generally recognized as safe.

We have recommended to the industry that it conduct literature research—that it conduct necessary research to resolve this question. We know that some work is being done but we are not sure just where the industry is on that point. At the same time, some of the government scientists are reviewing literature on arsenic to resolve this matter.

Diethylstilbestrol, also used in animal feeds, produces cancer when fed to test animals. We therefore are barred from approving further applications for permission to add diethylstilbestrol to animal feeds.

Incidentally, last year when the Congress was considering the cancer clause to the color additive amendment, we suggested that the provisions of the Delaney anticancer clause should not apply to a chemical used in animal feeds, provided the chemical did not harm

the animal itself and provided that under the conditions of use no residue of that material remained in edible tissues of the treated animal. That suggestion did not receive consideration by the committee considering the legislation. We don't know, of course, whether it will receive consideration in the next Congress.

If my chemistry hasn't failed me, polyoxyethylene monostearate is the chemical designation of the product I know as MYRJ 45; that is the chemical that we've heard so much about yesterday and today. If I may take the liberty to summarize what has been said about it, industry representatives say that the government has made a terrible mistake in holding that MYRJ 45 may not be added to food.

I hasten to come to the defense of the government. The Delaney anticancer clause says that a chemical may not be sanctioned for use in food if it induces cancer when fed to man or animals or if it induces cancer when tested by other appropriate means. The anticancer clause doesn't have the word "carcinogen."

Now, there's been a lot of discussion these two days about whether MYRJ 45 is or is not a carcinogen. This term is not used in the law. The question is whether, when you take a control group of animals and a test group of animals and you feed the test group a diet with MYRJ 45 added, and you feed the control group the same diet without MYRJ 45 added, the test group gets cancer and the control group doesn't. Now that happened when MYRJ 45 was tested. It clearly is a cancer-producer within the terms of the Delaney anticancer clause and it clearly cannot be sanctioned in food in any concentration.

Mr. Depew: Dr. Oser, would you like to comment on that question or the answer?

Dr. Oser: First, I should like to make a general statement on the question of whether a substance induces cancer. We all must recognize that the only limitation that is placed in this statute is "when ingested by man or animals" and there is no limitation on the amount ingested or the conditions and the period of ingestion and anything like that so this is, at present, without limitation.

But I might add: Isn't this just exactly a situation where the rule of reason ought to apply because these tumors that we are referring to in the case of MYRJ 45 arose in animals receiving 25 per cent of the substance in their diet.

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Now, I should also like to point out that the very same evidence on which this conclusion of MYRJ 45's inducing cancer is based was reviewed by the National Research Council's Committee on the Evaluation of Carcinogenic Hazards. It was also reviewed by the President's committee and, without unnecessarily lengthening this comment, I'd like to read just one short paragraph from the President's committee:

> Poly-oxyethylene stearate fed to rats at a level of 25 percent of the diet, but not at lower levels, produced urinary bladder stones which induced bladder tumors, some malignant.
>
> Since the cancers are always associated with the presence of stones, minute traces in the human diet are not likely to produce bladder cancer and can be treated as any other toxic material.

Mr. Depew: It is reported in the press that FDA has decertified and banned the use of Red No. 1 on suspicion it may be carcinogenic. Is it to be assumed FDA may arbitrarily take such action on other colors or additives merely on the suspicion that they may be carcinogenic or otherwise harmful?

Mr. Clark: The color was banned on the basis of liver toxicity—not carcinogenicity.

In relation to the second part of the question, the Food and Drug Administration would not delist colors for carcinogenicity without a thorough study of the scientific basis.

Mr. Depew: A question for Mr. Kirk: Is it true that food additive petitions are being considered as acceptable for filing in certain cases where information required under the statute—for example, reports of investigations to establish safety—is lacking? If so, is not the legality of any regulation permitting the use of such food additive subject to serious question?

Mr. Kirk: If we don't have the evidence I can assure you there's not going to be any regulation that will be the subject of any question. I know of no petitions which are being accepted for filing without the necessary information. As a matter of fact, the complaint I heard was that we seem to need more for filing than the folks want to submit.

I wonder if there's any question here about one thing that we did say. We have a regulation dealing with the submittal of published material. We did say, however, that if someone is referring to an article which was published by the Food and Drug Administration, we're not going to require you to send us a bunch of copies of that particular document. (Laughter)

Dr. Gordon: Can I make a comment? I think one encouraging thing to us scientists in industry has been the increasing emphasis in recent years in the Food and Drug Administration to establish their own research programs, not all of which are concerned with immediate regulatory problems. I'm only familiar with a couple of the items being done in nutrition, but I think this, to us, is a very healthy sign. It will make for much better scientific exchange; it insures that the government scientist keeps up to date besides the specific problems.

I think much more important, too, is that the industry matters on toxicology have always been on an eminently fair basis, though I want to make it clear from any other remarks I might have made that our problem is more with the way the laws might be worded than with the treatment we ourselves are receiving.

Mr. Depew: A question for Mr. Clark. It is noted that FD&C Red No. 4, FD&C Red No. 2, FD&C Yellow No. 6, FD&C Green No. 3 have not been cleared on two-year tests. These have been placed on extended testing.

(1) What is the status of these colors during extended testing?

(2) May we expect interim reports during the testing period?

Mr. Clark: I presume this question derives from the chart that was presented at the meeting on November 17, indicating that these particular colors are undergoing seven-year dog studies. Their status during any testing that's being done is exactly as listed in the provisional list and that is: They are at present under unrestricted use. I don't believe any special significance needs to be attached to their seven-year test program except that it is part of the testing program to determine their safety for use. We do not expect to publish interim reports on these studies.

Mr. Depew: A question for Mr. Goodrich: Is a product such as ice cream, made and sold without crossing state lines but made by a company that is generally in interstate commerce, subject to federal law—that is, to Food and Drug Administration jurisdiction?

Mr. Goodrich: It is not unless it is delivered to a customer for introduction into interstate commerce, in which case it would be both a criminal offense and the subject of a possible injunction for a local firm to deliver a violative ice cream locally to another firm who carried it in interstate commerce. But as long as the ice-cream maker made and sold his product and did all of his business within one state, he is

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not subject to federal jurisdiction simply because he is in interstate commerce in other products.

Mr. Depew: For Mr. Kirk: What is FDA's attitude toward industry-group-sponsored "qualified expert" panel expressions concerning the GRAS status of definite conditions of use for definite materials?

Mr. Kirk: I'm not quite sure that I understand the question. I'm afraid that I'd want to know more about this "qualified expert" panel before I'd try to comment. It just doesn't ring a bell with me.

Mr. Depew: The Food, Drug, and Cosmetic Act now regulates drugs—both for man and animals; food additives; color additives; and the various classes of pesticides and agricultural chemicals. Suppose a substance belongs in two or more of these categories. Is it necessary to file a multiplicity of applications and petitions or can the administrative process be simplified?

Mr. Kirk: We think we have simplified it. This comes up quite frequently with new drugs and food additives, antibiotics and food additives, food additives and pesticides, and some may recall we had one case where a product was a new drug, a food additive and a pesticide chemical all at the same time. One filing, as far as we are concerned, is enough to get the necessary regulations provided all the necessary information is in them.

Mr. Depew: The occurrence of bladder stones during the administration of an agent has been said to automatically place that agent in the carcinogenetic category because of the anatomical effects due to irritation. Is this necessary, or reasonable, when a dose response can be demonstrated and/or when the occurrence of the bladder stones can be related to solubility and doses of 100 or more times the exposure level do not produce this effect in long-term studies? Mr. Rankin, would you like to comment on that?

Mr. Rankin: I am not aware that anyone in the Food and Drug Administration has stated that the occurrence of bladder stones automatically classifies the material being fed as a carcinogen. I presume that the question relates back to the MYRJ 45 situation, in which cancers were produced in test animals that were being fed MYRJ 45, but we have made no statement that covers the field as this one does.

Mr. Depew: Dr. Oser, do you want to comment any further?

Dr. Oser: No.

Mr. Depew: When a tolerance is established under a food additive regulation, is the analytical method whereby it is controlled published or otherwise made available to interested parties, including consumer testing laboratories? Mr. Kirk?

Mr. Kirk: It is not ordinarily published but certainly it is available to anyone who is interested; just ask for it and we will see that you get it. Of course, in many cases the method would be in the books, such as those of the AOAC that are available to the public.

Dr. Gordon: I'd just like to comment that we recommend to most of our association members that it is advisable to publish all methods promptly in the accepted literature for just this reason, and we do so.

Mr. Depew: Thank you, Dr. Gordon.

A question for Mr. Clark: The language in the definiton for color additive ". . . is capable . . . of imparting color thereto" is very broad. Many substances "derived" from a vegetable, animal or mineral source have this capability. What is the interpretation of the FDA as to the scope of this definition? Does the definition include a great number of substances which have the requisite capability but which in the past have not been used primarily for their color?

Mr. Clark: Well, it's certainly true that the definition of color additive in the statute is a broad one and it was the purpose of Congress to so make it. We have stated in the proposed regulations (that Mr. Goodrich referred to) that a color additive would necessarily be one that actually transmitted color visible to the naked eye.

Even though it might not be a color additive it still might be necessary to consider as a food additive an article that did not actually color a food, drug, or cosmetic. We have tried in the proposed regulations to indicate that where a food such as chocolate carries its own color into a mixed food product, it will not be considered a color additive.

Mr. Depew: Another question for you, Mr. Clark: Can colorants other than those listed as safe be used for food-packaging applications, so long as they are not expected to become a component of the food? If so, what proof is needed that they do not become a component of the food and how can such opinions or concurrences be obtained?

How long a period would be reasonably expected to elapse before such opinions can be supplied by the FDA?

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Can such colorants be used in food-processing container or housewares in contact with food?

Mr. Clark: Well, that's partly been answered and that is that we've defined—excluded from color the definition of color additive—a product that does not transmit its color to the food. Again we must consider the possibility of its being a food additive even though it is not a color additive. In regard to the length of time for an opinion, I think Mr. Kirk has answered that. The answer would forthcoming just as rapidly as we could get it.

Mr. Kirk: You might use the Ramsay extraction studies to check on whether it migrates or not.

Mr. Depew: Thank you.

Another question for Mr. Kirk: Is it necessary to declare on a label an ingredient in very small quantity—for example, the tricalcium phosphate which is used as an anticaking ingredient in salt which is subsequently used at about 3 per cent in a product?

Mr. Kirk: Of course that must be declared on the label of the salt. Whether it has to be declared in a food to which the salt is added will depend on a lot of facts: what kind of a food; why it's there. Some of these anticaking agents have been authorized only for use in table salt; they have not been authorized for use in other kinds of salt, and should not be present in them.

Mr. Depew: A supplement to that question: What about small amounts of aluminum oxide (less than 200 parts per million) from grinding stones in a product?

Mr. Kirk: I'd like to talk to the scientists before commenting on that. [Later, FDA advised that while it is not concerned about the safety of less than 200 parts per million of aluminum oxide it would need more details before commenting on the legality of this situation.]

Mr. Depew: That concludes our question-and-answer session and the conference. I trust you all have enjoyed it and I think our panel here merits your thanks for their answers to your questions. (Applause)

Acceptance Statement of The Food Law Institute Scroll for the Food Protection Committee

By WILLIAM J. DARBY

In His Remarks at the FLI Dinner on November 28 in Honor of the Food Protection Committee, Dr. Darby Described Its Role Now and in the Future. He Is with the Division of Nutrition, Departments of Medicine and Biochemistry, Vanderbilt University School of Medicine.

THE MEMBERS of the Food Protection Committee of the Food and Nutrition Board, National Academy of Sciences-National Research Council—the present members and those who have retired from the committee—the many current and past members of the subcommittees of the FPC, the current and past members of the Industry Committee and of the Liaison Panel, and those American industries which have provided the academy with support for the activities of this committee all take pride tonight in the award which The Food Law Institute has seen fit to bestow upon the Food Protection Committee. We are justly proud that you should consider us worthy of the distinguished company of the previous recipients of this award.

It was but a decade ago that the Food Protection Committee was organized. And it is from the perspective of the decade that we may best assess the progress in this field—it is important not to appraise progress in the midst of a crisis!

Recall, if you will, those fitful days of the bread hearings, characterized by distrust, by sometimes poorly designed studies, by the reign of the "per se" clause, by the widespread concern for "poison and deleterious," by the confusion between toxicity and hazard—indeed, for the naïvete which characterized our outlook on this whole

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Dr. William J. Darby, Shown on the Right, Accepts the Scroll from President Franklin M. Depew of The Food Law Institute.

problem. Ten years hence many of today's critical issues will seem as remote.

Consider the progress of the intervening years: the legislative amendments—the Miller bill and the amendments to the Food and Drug Law which requires pretesting—the widespread recognition of the usefulness and validity of metabolic studies in providing a basis for assessment of safety, the attention given to the subject of food additives by the international agencies and the tremendous influence of their activities in this field, the maturation of the subject of toxi-

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cology of foods, the support for research available through such agencies as the Toxicology Study Section of the NIH, the better understanding of the considerations of carcinogenesis, and the ever-increasing understanding and good will, respect and trust between those powerful triumvirates of industry, government and university scientists.

The Food Protection Committee would be immodest to claim any major role in bringing about these developments. It would, however, be dishonest to deny a sense of pride and satisfaction in the contributions which it has made to progress in the field.

At the same time, it would be unrealistic not to acknowledge the many points which give us great concern for the future. May I indicate a few examples.

We must have much more attention by the scientific community to the basic problems relating to assessment of additives. We must have research on methodology. We must remain alert, flexible, youthful and imaginative in our assessments of scientific studies. We must be realistic and scientifically unprejudiced in our interpretation of data and, particularly, in projection of these results from the laboratory to their significance in the human. As individuals we must provide guidance for those responsible for the formulation of our laws and regulations, so that they may formulate protective measures which are not unduly restrictive.

Role of Food Protection Committee

What is the role of the Food Protection Committee now and in the future? Indeed, what do the words "food protection" signify? We have always interpreted them as signifying protection against debasement of our foods and protection of the health of our population resulting from contaminated or debased food substances.

In earlier years the function of a Food Protection Committee would no doubt have been to reduce the hazard resulting from bacterial contamination of foodstuffs or from deceitful debasement. During the past decade we have been concerned with the removal of the last possibility that additives might be harmful to the customer.

I see a need for the further evolution of our thinking aimed at attaining these latter goals. We have techniques for obtaining scientific answers to many of our questions today, but we are wanting in

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feasible and simple methods for assessing many properties of foodstuffs or additives. These we must develop, and the FPC may contribute thereto.

The FPC can aid further in codifying information on additives and much of its present effort is so directed.

More difficult, however, will be the education of the public at large concerning the gravity of our food situation. Present-day surpluses of food have given widespread credence to the notion that we are producing too much. Such an interpretation supports the view that we can afford to return to "the good old days," when one farmer worked diligently to produce sufficient food and fiber for three people instead of 25 to 29.

The United States Department of Agriculture has estimated that in order to meet the population increase expected by 1975, that is, 15 years hence, some 200 million additional acres would have to be in production if we assume today's productive capacity per acre to hold. We do not have 200 million additional acres of land for cultivation. We do not have trained or educated farmers to manage such acreage. Fewer persons yearly are entering farming as a career. But fewer insects, rodents and other sources of loss of agricultural products are not pertaining. Neither is there a decrease in the number of misinformed individuals relative to foods. The vocal followers of Longgood, of Rodale, of Sir Albert Howard, of Estelle Davis are constantly making themselves heard in legislative and other groups.

In order that the United States and the world at large may have an adequate food supply, we each as individual scientists have a personal responsibility and, collectively, a moral obligation to support and prosecute research, to make available in a completely unbiased and responsible manner the findings of our studies, and to interpret these findings objectively. We have a further responsibility to examine our laws and regulations and proposed new legislation in light of our knowledge of science and of food needs of our population today and tomorrow, and to make certain that these laws and regulations are such as to assure the fulfillment of needs and to permit scientific agriculture and food industry to provide the most wholesome, nutritious, safe, attractive, acceptable and economical foods to nourish in all good health the ever-increasing population of this country—and to set the pattern which other less fortunate nations may follow.

[The End]

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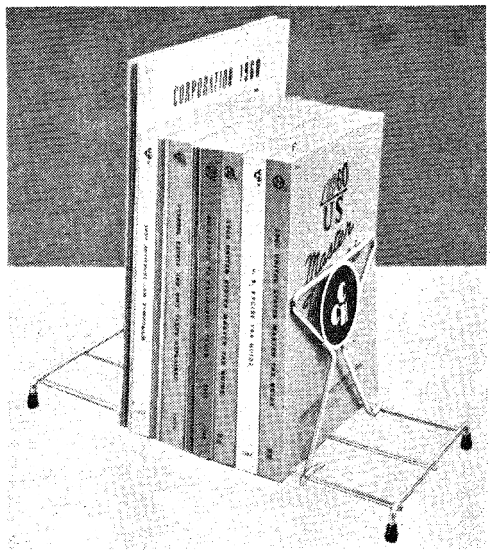

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