VOL. 16, NO. 2 FEBRUARY 1961

Food Drug Cosmetic Law JOURNAL

Papers Presented at the Morning Session of the Sixteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, January 25, 1961

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.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $20 per year. Single copies are $2 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

February, 1961

Volume 16 • Number 2

Second-class postage paid at Chicago, Illinois.

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TO THE READER

About This Issue. — The Sixteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association was held on January 25, 1961, at the Meeting Hall of The Association of the Bar of the City of New York. Papers delivered during the morning session are published in this issue of the JOURNAL; those presented at the afternoon session are scheduled to appear in the next issue.

The section chairman, *A. M. Gilbert* of New York City, presided. The first speaker was *John L. Harvey,* Deputy Commissioner of Food and Drugs, who spoke on the "Evolution in the Food, Drug and Cosmetic Law Area." The Assistant General Counsel for Food and Drugs, *William W. Goodrich,* spoke on "Legal Developments in 1960 Under the Federal Food, Drug, and Cosmetic Act."

These two HEW officials were followed by a representative of the Federal Trade Commission, *Charles R. Moore,* who serves as assistant director on deceptive practices in the FTC's Bureau of Investigation and who discussed the regulation of deceptive practices by the FTC.

Kenneth E. Mulford concluded the morning session with his description of the role of men of science and lawyers in lawgiving. Mr. Mulford is assistant to the executive vice president of the Atlas Powder Company, Wilmington, Delaware.

Papers were presented that afternoon by William J. Condon, George M. Burditt, Vincent A. Kleinfeld, Thomas W. Christopher and Franklin M. Depew.

Also included in this issue of the JOURNAL are a translation of Chapter IV of the Latin-American Food Code, dealing with its application to containers of all kinds, and a report on the Sixth Symposium on Foreign Matters in Foods, which took place in Madrid, Spain, last October. Our reporter is the JOURNAL's Associate Editor for Europe, *Dr. Ernst Abramson,* formerly director of Sweden's National Institute of Public Health. He is now professor of physiology at the Carolina Medico-Surgical Institute and at Upsala University.

Watson B. Miller.—Watson B. Miller died on February 11, 1961, at his home in Washington, D. C. He was 82 years old. He had had a long career in health and welfare work. In 1941 he was appointed assistant administrator of the Federal Security Agency and became its director in 1945. As head of that agency he supervised the United States Office of Education, the Public Health Service and the Social Security Administration. It was the predecessor of the Department of Health, Education, and Welfare. He left the agency when he was named United States Commissioner of Immigration in 1947.

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Food·Drug·Cosmetic Law
Journal

Introductory Statement:

Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association

By A. M. GILBERT

Mr. Gilbert, of New York City, Is the Chairman of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association. He Was the Presiding Officer at the Sixteenth Annual Meeting of the Section, Which Was Held in New York City on January 25, 1961.

I AM HAPPY TO WELCOME all of you to the Sixteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association and am glad to note such a fine attendance. As you know, this section is the pioneer and oldest bar association group of lawyers in the food and drug field and our membership is not limited to New York State but, rather, is a nationwide one.

Our program today consists of nine interesting and valuable papers; I am confident that all of you will find the papers and the discussion that we will have at the end of the morning and afternoon sessions most rewarding. On behalf of our entire membership, I want to express our appreciation to all of the speakers on our program for their cooperation in preparing their papers, coming here today to read them, and subjecting themselves to questioning from our members.

Before proceeding with the formal part of our program, I would like to make some brief observations about some of the developments of interest to us since our last annual meeting. I should first refer to the food additives amendment which became effective last March. This has given all of us, both inside and outside the government, numerous new and challenging problems and has caused many of us to spend countless hours in our efforts to solve or cope with these problems—many of them unexpected.

In addition to the promulgation of several food additives orders, the United States Food and Drug Administration has extended the effective date of the amendment for hundreds and hundreds of substances to March 6, 1961, which date is fast approaching us. We know that it will be impossible to have food additives orders for all of these substances for which the effective date of the amendment has been so extended. On the other hand, FDA has no statutory authority to grant any further extensions. Accordingly, it has been gratifying to learn that just within the past few days, FDA has prepared and has sent to Congress a proposed bill which would give it the power to grant further extensions under certain circumstances. We have not as yet had a chance to study this proposed legislation in detail, but I know that our membership as a whole is generally in favor of giving FDA the right to grant further extensions. We must be careful that disagreement as to the provisions of this proposed bill should not cause the bill to be lost or not enacted in proper time. I would suggest that our section, through an appropriate committee, study the proposed bill as carefully as possible and if it feels there should be any changes in it, it should attempt to work these out with FDA so that there will be no disagreement between government and industry when these bills are considered by the appropriate committees in Congress and by Congress itself. It is imperative that the law be amended before March 6, 1961, so that further extensions may be granted.

During the past year, another amendment to the Federal Food, Drug, and Cosmetic Act has been enacted. I refer, of course, to the color additive amendment. We are awaiting the promulgation of regulations under this amendment (I understand that proposed regulations have just been published in the *Federal Register*) and we certainly all hope that the regulations in final form will be as realistic and as helpful as possible, in keeping with the expressed objective of this amendment as well as the legislative history supporting it. I know

that all of us, both inside and outside of government, expect that we will be having numerous and difficult problems to resolve with respect to the color additive amendment but, as in the case of other new legislation we have experienced over the past years, we are confident that these will be worked out in a fair and equitable fashion and in a way with which all of us can live.

Federal Hazardous Substances Labeling Act

I should also note that since our last meeting there has been enacted the Federal Hazardous Substances Labeling Act, which was signed by the President on July 12, 1960, to really become effective February 1, 1961. While this is not an amendment to the Federal Food, Drug, and Cosmetic Act, it is of considerable importance to a substantial part of our membership and to their clients and companies. As you know, this act is patterned on the Federal Food, Drug, and Cosmetic Act; is to be enforced and administered by the Food and Drug Administration; and involves many of the problems that we have under the Federal Food, Drug, and Cosmetic Act. I suggest we should consider that this act and problems arising under it are proper for consideration and deliberation by this section and I trust that from time to time in the future we may have one or more papers with respect to this act read at our meetings. Along somewhat similar lines, certain problems under the Federal Insecticide, Fungicide, and Rodenticide Act—especially as they tie in with the sections of the Federal Food, Drug, and Cosmetic Act dealing with pesticide chemicals—are becoming of increasing importance to our members. Incidentally, it would be a challenging assignment to a committee to suggest an appropriate new name for our section so as to indicate our interest and concern not only in the Federal Food, Drug, and Cosmetic Act, but also in the Federal Hazardous Substances Labeling Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and the Meat Inspection Act—not to mention the subject of product liability.

I have been led to believe that there will be an extension of the effective date of the Federal Hazardous Substances Labeling Act past February 1, 1961, and perhaps one or more of the speakers to follow will talk about this as well as about legislation to authorize extensions of the effective date of the food additives amendment.

While the food additives amendment is in mind, permit me to refer to one problem under it that keeps cropping up. As you know,

FDA has been asked, upon more than one occasion, whether it feels that a tin can, to be used for food packaging, which contains an unauthorized food additive is immediately subject to the Act and whether such a tin can is a food additive. Another aspect of the same question is whether a substance not in and of itself food, but which is being shipped to, let us say, a paper manufacturer to be used in the manufacture of paper which in turn will be used for the packaging of food, is a food under the Act. Perhaps questions of this kind are more important from a legal aspect than from a practical one. But I think they are of real interest to our membership. In such connection, it is to be noticed that FDA recently published a food additives order for packaging starch, which is not to be used as such as an ingredient in food but in connection with the manufacture of packaging materials. The order required, among other things, that packaging starch be labeled with the "other information required by the Act." I do not know whether this provision was an unintentional carryover from the order for modified starch (which is to be used as such as an ingredient in food) which was published in the same issue of the *Federal Register* or whether, by such language, FDA means to take a firm position that such an indirect additive is a food and must be labeled as such under the Act.

Perhaps the officials of FDA who are here today will talk about this during the course of reading their papers, or this may be discussed in our later questioning periods. In any event, I believe that, as lawyers, we are interested in having this point clarified and disposed of in an accurate fashion.

Report of Kendall Committee

I know that all of us are gratified that the recent report of the Kendall Committee gives FDA a clean bill of health. While our membership did not need a Kendall Committee to disclose the outstandingly efficient, honest and devoted manner in which FDA has been performing its duties and responsibilities, it still is good to have on the record the report of this investigating committee. Our confidence in FDA and its integrity has never wavered for an instant and perhaps it would be advisable for our section to adopt a resolution on this subject today, even though our section and the American Bar Association Division of Food, Drug and Cosmetic Law have previously stated their position from time to time in the past.

We are also gratified to learn that, following the issuance of the Kendall Committee report, the new departmental rules adopted for FDA (which probably are really not new in any respect) definitely indicate that FDA will continue with its "open-door policy." We have always felt that this open-door policy has been of distinct advantage and benefit to the consumers of this country as well as to government and to industry and it would indeed be a disservice to all parties in interest if it were ever modified.

Landis Report

I know that most of you have had a chance to read the Landis report to the new President, dealing with regulatory agencies. Among other things, this report recommends that most—if not all—of the functions, responsibilities and activities of FDA under the Federal Food, Drug, and Cosmetic Act be transferred to the Federal Trade Commission. With all due respect to the Federal Trade Commission, I do not believe—and I feel confident that our membership agrees with me—that any such transfer should be made. The Administration is undoubtedly the government agency best organized and most qualified to administer and enforce the Federal Food, Drug, and Cosmetic Act. I recommend to our membership that it consider the advisability of adopting a resolution on this particular subject.

Furthermore, I also recommend to our membership the adoption of a resolution advocating that FDA be kept on a career basis, as it has been since its very inception. This career system has been very valuable to all parties concerned, including the consumers of our country. This section and the ABA Division of Food, Drug and Cosmetic Law has stated its opinion on this subject in the past. However, we now have a new Presidential administration and a new Secretary of Health, Education, and Welfare and, while I see no indication of any change, I think it advisable that this section express itself on this particular subject at the present time.

Budgets

Shortly before the inauguration of President Kennedy, the former administration presented to the Congress the budget for the coming year and we are glad to note that in the case of FDA, it calls for an increase of about 20 per cent, which would make FDA's budget about $25.4 million and call for about 2,500 members on FDA's staff. It also

appears that it is projected that, through 1966, FDA's budget will be increased to about $44.2 million and call for a staff of something over 4,800 people. This section and our ABA counterpart have always advocated appropriate increases in FDA's budget and we are gratified to note these developments. We hope that the new administration or Congress will not effect any reductions in the figures I have just mentioned. As pointed out so clearly some years ago by a citizens advisory committee, FDA needs sufficient funds, staff and facilities to fulfill its obligations under the Act; even with the figures I have just mentioned, FDA will not have any surplus. I should comment, in passing, that we hope that in filling the new positions that will be available out of the extra budgetary allowances, FDA will be able to engage competent and devoted people. We recognize the difficulties in this regard but we know that, based upon past performance, FDA will extend its utmost to build a highly qualified staff. Perhaps, in turn, this increase in budget and additional staff will permit FDA to reduce many of the delays we have all been experiencing during the past year or so and which we recognize have not been the fault of FDA but, rather, the result of an insufficient staff for the amount of work involved.

While talking about budgets, we also note that it is proposed to increase the budget of the Federal Trade Commission from $8 million to $9.6 million. When we bear in mind the numerous responsibilities of the Federal Trade Commission, including those dealing with false and deceptive practices and antitrust problems, we must all agree that even $9.6 million is an insufficient sum for the Federal Trade Commission in order to enable it to perform its statutory responsibilities in proper fashion. Perhaps there should be a citizens advisory committee organized to review the Federal Trade Commission picture and make recommendations. Such a committee was of great benefit in the case of the Food and Drug Administration and perhaps there could be similar results with regard to the Federal Trade Commission. Like all of you, I do not know who will be the next chairman of the Federal Trade Commission, but I would like to suggest to Mr. Moore of the Federal Trade Commission, who is with us today, that if he sees fit, he might like to pass on this suggestion to the new chairman after he has been appointed.

I know all of you are looking forward to hearing from our speakers and, accordingly, we will now proceed with the formal part of our program. **[The End]**

Evolution in the Food, Drug and Cosmetic Law Area

By JOHN L. HARVEY

The Author Is Deputy Commissioner, Food and Drug Administration. In This Paper Before the Sixteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association on January 25 in New York City, Mr. Harvey Discusses Those Changes in the Administration of Federal Food and Drug Laws That Greatly Impressed Him During His 35 Years of Enforcement Work.

THERE IS a profound and continuing change going on in the administration of the federal food and drug laws. This is having a significant impact upon what we do to achieve the high purposes of these laws; it affects the number and kind of legal actions which we bring and which are brought against us and it influences the makeup of the Food and Drug Administration. The change is so gradual that unless one stops to look back over the past few years, he can easily miss it.

Having been in federal food law enforcement work for more than 35 years, I have had an opportunity to see the evolutionary process firsthand. I want to discuss with you some of the changes that have impressed me.

When I came with the old Bureau of Chemistry with the Department of Agriculture in 1925, the food and drug laws were still in what might be termed "the Harvey W. Wiley era." The 1906 Food and Drugs Act was still on the books. Although some efforts had been made to keep it up to date and make it a more workable regulatory tool, it still was couched in generalities so that both the enforcement official and the regulated industry frequently had difficulty in deter-

mining exactly what was required. There were a number of broad loopholes which allowed the unscrupulous, in many cases, to escape effective controls—for example, the provision that required the government to prove fraud before it could take action against false and misleading therapeutic claims on drugs and the "distinctive-name joker" under which any mixture or compound of food not injurious to health could escape control—it is not difficult to understand why this Wiley era, which extended into the "Walter G. Campbell era," was a time of spectacular court contests, often leading to spectacular appeals.

In the 30's, which may be termed "the Campbell era," two significant evolutionary steps got under way. There was a growing awareness that the 1906 law needed a complete overhaul to close the gaps in consumer protection and to deal with the new problems of food and drug technology. As you well know, in the five-year period from 1933 to 1938, there was intense activity on Capitol Hill, in the executive branch and in industry, which culminated in the Federal Food, Drug, and Cosmetic Act of 1938. The enactment of this law, despite the numerous serious conflicts that had developed during its stormy passage, was a near miracle that reflected the power of an aroused public opinion. The second evolutionary step which began in the 30's, was the development of administrative techniques to handle some of the more complex problems of food standardization, food and drug labeling, and advance assurance of the safety of food and drugs.

As I have already implied, the 1938 law is much clearer than the law it replaced, and it provides for the establishment of rules that are even more specific in describing the conduct and activities that will constitute a violation. For example, we were given authority to issue regulations specifying fully informative labeling for special dietary foods; to establish definitions, standards of identity and reasonable standards of quality and fill of container for most foods; and to issue regulations describing in considerable detail the labeling that must be applied to drugs to insure that they will be both safe and effective for their intended uses; and we were given our first authority on advance clearance of new drugs to assure their safe use. In the cosmetic field, the law is not quite so specific, but this is understandable in view of the fact that cosmetics were brought under the statute for the first time.

We will shortly look at the amendments which have become necessary since 1938 to enable us to meet our responsibility of protecting the public health and purse.

The Wiley era and the early part of the Campbell era, extending roughly from 1906 to 1938, constituted a period in which laws were laid out in broad strokes by the legislative branch of the government. The details were filled in by the judicial branch through specific court decisions. The courts in fact, if not in theory, continued to write the food and drug laws by interpretation for years after the statute was enacted. Only through this case-by-case process did the laws take on enough specificity to enable a manufacturer to know what was required.

Under such circumstances it is understandable that, in the majority of contested legal actions, the contest was over specific facts which the government alleged constituted a violation of the law, but which the defendant or claimant of the seized merchandise believed did not. It can be truly said that it was somewhat difficult even for the well-meaning manufacturer to comply with the food and drug requirements during the Wiley era and early in the Campbell era.

Marked Change in Today's Situation

Today the situation has undergone a marked change. The laws enacted by the Congress still are expressed in considerable generality, but the Congress is relying more and more upon the administrative agency to interpret the statute and pinpoint the actions that will be and will not be tolerated through the administrative rule-making process. For example, a new drug may be marketed legally only after evidence concerning its safety has been submitted to, and accepted by, the Food and Drug Administration. There is little, if any, room for confusion on the part of the would-be manufacturer of a new drug; the certifiable antibiotic and insulin may be marketed only in accordance with regulations that set forth in detail conditions that must be met and only after a sample from the lot in question has been examined by the Food and Drug Administration and found acceptable. The pesticide regulations set forth in detail the allowable quantities of permitted pesticides that may remain on crops when they are marketed so that all one has to do to determine whether his crop is legal from the standpoint of pesticide residues is to make an appropriate analysis. In food additives, a comparable development has taken place. Under the amendment passed in 1958, we determine upon request or petition the condition under which a food additive may safely and legally be employed and we issue a regulation stating these conditions for all interested parties.

The net result is that law compliance is becoming easier for the individual who wishes to abide by the law. He doesn't have to wonder whether a product that he is going to market will be interpreted by the courts as meeting the requirements of the Food, Drug, and Cosmetic Act in those numerous cases where, following the administrative rule-making process, we have established by regulation the exact conditions that will constitute law compliance.

Heavy Burdens Placed on FDA

At the same time this evolution has placed very heavy scientific and legal burdens upon the Food and Drug Administration. In order to evaluate adequately the very complex scientific data being submitted in support of new drug, pesticide, food additive, and color additive petitions, we must have scientific personnel with an unusual degree of competence, and our scientists must be able to understand the most recent advances in food sophistication, drug therapy, color chemistry and packaging technology. Our field chemists are facing the new problems of control. They must have the equipment and the know-how to conduct control analyses for everything from a packaging film to the latest surfactant.

A few years ago when we studied the use of chemicals in food in preparation for our testimony for the Select Committee of the House to Investigate the Use of Chemicals in Foods and Cosmetics (the Delaney Committee), we ventured the opinion that about 750 to 800 chemicals other than commonly accepted food ingredients were being employed. Some scoffed at this figure, believing that it was far too high. We now know that it was far too low. We have already extended the effective date of the food additives amendment for more than 3,000 uses of chemicals that industry believes may require attention under this statute. Some of the materials for which extensions have been granted are extremely toxic materials that, if used at all in the food-processing operation, will have to be used under the most careful and effective safeguards. The extension list goes all the way from activated charcoal complying with the requirements of the *National Formulary* through such materials as ethylene oxide, oil of pennyroyal, turpentine, formaldehyde, and zinc sulfide.

No one in the United States had a full understanding of what was going on in food and packaging chemistry before the enactment of the

food additives amendment. Knowledgeable people in industry knew, of course, what new chemicals they were using. They probably had a pretty good idea what their competitors were using. But they did not have a full picture as applied to the entire food and packaging industry. We in the Food and Drug Administration, as already indicated, did not recognize the full extent of the use of new chemical substances, in connection with food production and handling, even after we made a careful study of the available facts some years ago.

Revolution in Food and Packaging Technology

The truth is that a complete revolution in food and packaging technology has been taking place in the past few years, and it is continuing. Especially in the paper, packaging and plastic industries, the amendment stimulated the new awareness of the necessity for checking all substances that come in contact with food from using them. The reason, of course, is not solely the enactment of the food additives amendment. The food industries have always wanted assurance that their packaging materials are safe. But now they are insisting that the substances they use in food and food packages be cleared with the government for safety.

Redirection of Inspection Effort in Field

These major developments not only require scientific staff in our Washington laboratories and our administrative offices, but also require a redirection of our inspection effort in the field. We require field chemists who can analyze for a tremendous variety of chemical substances that can be present in foods and drugs in quantities measured in parts per million. They must be able to extract these small amounts from food and drugs, and then identify and measure them precisely. We require field inspectors who are trained to recognize the wide variety of chemical substances that may be employed in the food industry and to detect uses which are not permitted or which may result in illegal residues. Again these are abilities that we have had in the past, but we must have a greatly increased staff in the field to do an effective job of administering the new rules.

The bulk of our efforts in the administrative and legal fields are likewise being devoted to this rule-making process that has become so important today. Between 1938 and 1954, we established, by the old rule-making procedures, one formal tolerance for a poisonous

substance in food. This was the tolerance for fluorine on apples and pears which was later declared invalid by the courts. We had a very few informal tolerances—for example, for lead and arsenic on apples and pears—which were not fully effective as regulatory tools. Since the enactment of the pesticide chemicals amendment in 1954, we have established more than 2,000 individual tolerances for well over 100 pesticide chemicals for a variety of crops. It is quite apparent that there will be a similar flow of regulations for food additives.

Last year a very large proportion of the time of the top management of the FDA was spent on regulations and problems that arise from the rule-making procedures. It is a matter of some satisfaction to us that we have been finding it possible to increase the consumer protection available under the Food, Drug, and Cosmetic Act by rule-making through which the requirements can be made clear to all who wish to comply.

I do not mean to imply at all that the conventional legal actions in the federal courts are coming to an end. The crucial phase of this new look in the food-law field will come as we proceed with the enforcement of the regulations we are issuing. There will be some firms that fail to abide by the new rules and there will be continuing necessity for legal actions because of such noncompliance.

The pesticide, food additives and color additive amendments, all enacted in the last six years, present a serious challenge. We are assigned the heavy task of so restricting the use of additives that directly or indirectly enter our foods that no harm can come. We can meet this challenge, and thus protect the public health, only to the extent that we have good scientific appraisals of good scientific data to help us in drafting the rules for permissible use of additives; good inspectional techniques to detect any misuse of additives; and means of enforcing the established rules. We must have all of these things if this new approach to food safety is to succeed.

It is important for us all to realize that the facilities must be available to provide the three essential steps in regulation through administrative rule. We must have enough technical and other factual information, we must study and soundly evaluate this and formulate the rule and we must systematically enforce the rule on a basis that gives adequate assurance to all that the rule is being followed, and not disregarded. In a sense, we cannot limit the number of the players—but we must field all of the balls. **[The End]**

Legal Developments in 1960

UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

By WILLIAM W. GOODRICH

In His Speech Before the Recent Meeting of the New York State Bar Association, the Author Stressed the Developments Made by the FDA in the Area of Food and Color Additives. He Is Assistant General Counsel for Food and Drugs, Department of Health, Education, anc Welfare.

THE PAST YEAR has been one of tremendous significance to the growing effectiveness of the nation's food and drug laws. Three or four papers would be required to report in any depth all that has happened. My time will permit a review of only the highlights.

Old and New Problems

Some of our old problems have been finally solved. The Hoxsey Cancer Clinic in Dallas has been closed; new life was snuffed out of the Koch cancer treatment when we promptly obtained an injunction against a distributor who tried to revive it; and we completed a seven-year struggle to enjoin the distribution of the Tri-Wonda treatment for arthritis and rheumatism.

Other old problems—such as misleading vitamin promotion, sale of falsely represented weight-reducing preparations, and roadside distribution of amphetamines—were still with us, demanding full-time efforts. They were far from being under fully effective control.

However, the most far-reaching developments occurred in the passage of the new color additive amendment and the hazardous household substances labeling law. These laws added many new responsibilities to the already complex duties assigned to the Food and Drug Administration by the food additives amendment of 1958.

New problems of considerable magnitude and importance arose under the original act in improving the reliability and the labeling of prescription drugs and in strengthening our new-drug operations.

Color Additive Developments

The developments with respect to color additives alone were enough to make 1960 a year to remember, but, because of all the other things that concerned us, we cannot call it "the color additives year." The mere mention of Red No. 1, lipstick dyes, folic acid, safrole, diethylstilbestrol, potassium permanganate, dihydrostreptomycin and the Delaney anticancer clause will call to mind the scope and the rush of recent events.

In the area of color additives, the year started with the announcement of a hearing to remove 14 D&C coal-tar colors from the harmless list, and the publication of a final regulation canceling all outstanding certificates on a series of seven FD&C colors that already had been removed. The hearing on the D&C colors was held, a tentative order announced, but the colors were saved—temporarily, at least—when they were deemed provisionally listed on the date of enactment of the new color additive law. After its passage, restrictions and temporary tolerances were imposed to permit the safe use of the D&C colors, primarily in lipsticks, during the transitional period.

Our cancellation of the certificates precipitated judicial review in the Court of Appeals for the Second Circuit, where the Department's action was sustained. The Department has the authority it claimed, to cancel and revoke any batch certificate for a coal-tar color it previously has issued, whenever the harmlessness of the color is adequately drawn into question. Ironically, Red No. 1 escaped this cancellation order temporarily because no precise finding that the color was toxic had been made, only to fall a short time later when additional pharmacological data clearly established that the color was a live poison to test animals.

Delaney Clause

The big story of the color additive amendment was, of course, the retention of the Delaney anticancer clause. The clause was strongly supported by the Department; the House committee heard an expert panel on the cancer problem; and it considered the Kistiakowsky report. The clause was retained with only an amendment

which provided for the referral, for advice, of any question arising because of it to an *ad hoc* advisory committee of experts.

Current Situation

After the amendment was passed, the Department prepared provisional listings, imposing some restrictions and tolerances; struck Red No. 1 from the list; and canceled the certificates that had been issued for it. We then published a draft of interpretive and procedural regulations to place the new law into operation. We urge everyone to study the draft regulations and to offer constructive criticism of them. We also called for use and safety data on which to base additional temporary tolerances. Use information was submitted by January 1, 1961, and is now under study. We doubt that it is complete. No new safety data was offered. We have outlined our program for testing colors over the next two-year period, and we have called upon those affected outside government to do the rest of the job. This is where the matter now stands.

Food Additive Clearance

The transitional period for food additives drew near to a close in 1960. But the Department has recommended legislation for a further extension of the effective date to allow us and the industries concerned more time for the establishment of the needed safety regulations. The magnitude of this problem is far greater than ever anticipated. Instead of several hundred additives we thought would need clearance, there are a few thousand and, seemingly, no one can sell any package or any processing equipment, or the materials going into them, unless FDA has first cleared the substances for safety. This has created many problems in the development and study of data and the preparation of regulations to assure the safety of all these indirect and incidental additives, as well as regulations dealing with the purposeful addition of chemicals to food. The major stumbling block so far to the establishment of the safety regulations has been that the petitions submitted to us, for the most part, are incomplete and thus inadequate, despite the rather specific details set out in our regulations describing what we must have to establish safety for use.

Extension Legislation

Our proposed extension legislation is based on these fundamentals: First, no extension may be granted for any additive for

which the initial steps to establish safety were not undertaken before March 6, 1960. Such additives, will be adulterants after March 6, 1961, even though they were in commercial use on January 1, 1958. Second, extensions will be granted on an individual-substance basis when a finding can be made that the extension involves no undue risk to the public health, that it is necessary and that bona-fide efforts are being made to establish scientifically either that the substance is not a food additive or, if it is, that its use will be safe.

The extension may be continued so long as the study is being pursued with reasonable diligence. But it may be terminated by the Department upon a finding that it should not have been granted in the first place or that because of changed circumstances the extension is no longer safe or necessary or that there has been a failure to submit required progress reports or to meet any other condition that may be attached to the extension.

Folic Acid and Safrole

Folic acid and safrole provide us with case histories on how extensions will work. Folic acid was widely used in vitamin supplements for several years prior to January 1, 1958. It was proposed, but not listed, as a substance generally recognized as safe (GRAS). The Administration, early in 1960, informally expressed the view that at levels up to 400 micrograms per day it would be GRAS. But reports which began to appear in the medical literature indicated that even at this level it might possibly mask the blood symptoms of undiagnosed and untreated pernicious anemia while allowing neurological damage from the disease to progress. This carried a threat of paralysis to the very small number of people with this disease undiagnosed, who might be taking vitamin supplements without medical supervision. After consulting two groups of experts, FDA issued a statement that folic acid at any level in vitamin supplements is a food additive, that the effective date of the law could safely be extended for folic acid at 400 micrograms per daily dose until March 6, 1961, and that after that date vitamin supplements containing any amount of folic acid could not be marketed without an effective regulation. The burden of proof of safety is on those who propose to use folic acid after next March.

Whenever the safety of a long-used additive is drawn into question, it is a food additive and cannot be lawfully used unless there is a regulation permitting it, or an extension. The extension may

be granted for as long as its scientific support will allow, but it may be terminated forthwith when new evidence requires.

Safrole, a flavoring used in root beer, was withdrawn voluntarily from the market during 1960, on the basis of recently completed scientific work which showed that this old flavoring is a "weak hepatic carcinogen." Prior approvals were revoked and extensions of the effective date of the law were denied.

The fact, therefore, that a substance has long been used in food and has an extension under the food additives amendment does not disable the government from moving against it when facts show that it can no longer be used without undue risk to the public health. Nonetheless, the proposed extension legislation will allow time for both industry and FDA to clear up the safety questions on a great many substances on which a final decision cannot now be reached.

Developments in Drug Field

Most of the developments in the drug field are related, perhaps, in the public mind to the Kefauver hearings. Undeniably, the hearings hastened what has been done, but we had long recognized, and had begun to cope with, inadequate and misleading promotional material for prescription drugs. Also, we had been reviewing the new-drug operations to close any defects found. Indeed, before the Kefauver hearings we had initiated a criminal prosecution against a testing laboratory which supplied false data about drug assay to the holders of new-drug applications for submission to us.

Recent Regulations

The regulations we recently have made effective were drawn to require a full disclosure of all side effects, contraindications, warnings, cautions, and untoward reactions on any promotional piece that gives any information as to what the drug is for or its recommended dosage. The regulations also proposed to require that the approved brochure be included in the market package of most prescription drugs. This requirement is still under study, since several alternative methods have been proposed for accomplishing the same result.

New Improvements

The regulations made several improvements in the new-drug operations, principally providing for complete factory inspection when

necessary to reach a safety decision before the new drug is made effective, and that all advertising and promotional materials used for new drugs be substantially the same as what has been approved through the new-drug clearance procedures. There are, of course, other details in the new regulations, but these are the principal features.

Hearings on Proposed Revocations

One point of possible significance in the new-drug area is that two hearings on proposed revocations have been scheduled during the past year, the first actually to proceed to the hearing stage in many years. The drugs involved are diethylstilbestrol in poultry implants and furazolodone, an antibacterial agent. Thus far, no drug has attempted to stay on the market through the hearing process in the face of the New Drug Branch's opinion that it is not safe.

Appellate Cases

Finally, there are three appellate cases to be watched. The ice cream standards are under attack by four petitioners in San Francisco. The Third Circuit has under submission an important slack-fill container case, questioning the use of hollow dividers in a candy box, ostensibly to protect the contents, but incidentally adding significantly to the length of the box. Also, we have appealed to the Second Circuit a case involving our right to seize adulterated and misbranded food which was prepared from interstate components none of which were in violation when shipped. The local manufacturer is alleged to have adulterated and misbranded the food while it was held for sale after shipment in interstate commerce. The great issue in the case is whether federal jurisdiction extends to locally prepared fabricated foods in which interstate ingredients were used. If it does not, as the district court held, there is an important weakness which may affect the safe use of food additives, color additives, and new drugs in animal feed, as well as open the way for other violations having only economic consequences.

Summary

As this brief review indicates, FDA enters the new year with grave responsibilities and with a multitude of problems clamoring for solution. In doing an effective job, we will need all of the help and support we can get. **[The End]**

Regulation of Deceptive Practices by the Federal Trade Commission

By CHARLES R. MOORE

Mr. Moore Is Assistant Director on Deceptive Practices, Bureau of Investigation of the Federal Trade Commission. The Comments and Observations in This Statement—Made Before the Food, Drug and Cosmetic Law Section of the New York State Bar Association —Are the Author's and Do Not Necessarily Reflect the Views of the Commission or of the Author's Colleagues on the FTC Staff.

OUR NATION IS UNIQUE in the annals of history because it has certain distinctives—distinctives that our founding fathers supported by their lives, fortunes and sacred honor. Old nations with greater national resources and much larger population, but hampered by traditions and institutions of their past, could not surge forward. But our infant republic, born of 13 independent colonies and less than 4 million free souls, inspired by the great spiritual and material advantages that were so remarkably expressed in our Declaration of Independence and so skillfully implemented by our written Constitution, utilized favorable geographical location and the capitalistic system of economy to accomplish miracles of self-development and material strength which outstripped the world in a few ticks of the clock of civilized history. We of succeeding generations must not lose sight of these American distinctives, this great heritage, nor let our business methods tarnish and lessen their appeal to succeeding generations.

Totalitarian theorists urge now, as they did in colonial days, that the principles of individualism and free enterprise are impractical and that our system of checks and balances is too inefficient to withstand complex internal forces and external pressures. But

our experiment in government has proved that there is a happy medium between totalitarianism (be it Marxian or other form) and anarchy and that individualists can use combinations to achieve limited aims and also preserve a maximum of individual choice. Limited restraints can be placed on the actions of business concerns and individuals without destruction of initiative and basic freedom. It is a part of our philosophy that power is best exercised when it is widely dispersed, irrespective of whether that power be in the state or in its citizens or corporate bodies.

The profit motive has sparked individual initiative and daring to produce material benefits that have exceeded the capacity of totalitarian economists to dream. Experience has shown, however, that there must be some restraints on this stimulus, for some would not follow ethical lines of conduct in the market place. It was out of this concept and this background that the laws administered by the Federal Trade Commission grew.

Basic Purposes of Laws Administered by FTC

These laws have as their basic purposes the preservation and promotion of our free enterprise system of economy by (1) keeping it open to all who wish to enter and keeping it fair from a competitive standpoint and (2) protection of the public from unethical business practices. Economic freedom is basic. Other freedoms cannot long survive termination of the free enterprise system of economy. There are a number of other federal statutes having the same general purpose as have the laws administered by FTC, but no one government agency has such broad authority and responsibility in this connection as does this Commission.

The Commission's armamentarium for accomplishing these purposes consists of the Federal Trade Commission Act, the Clayton Act, the Webb-Pomerene Act, the so-called "truth in fabrics and furs" statutes and the Lanham Act. The McCarran-Ferguson Act limits the Commission's jurisdiction over insurance. The Federal Trade Commission and Clayton Acts are, as you know, the most important of these laws.

The regulatory activities of the Commission are broadly divided into two fields, that is, monopoly and deceptive practices. It is my purpose to omit the monopoly work, which is under the Clayton

Act, the Webb-Pomerene Act and Section 5 of the Federal Trade Commission Act, and discuss our current efforts in the deceptive-practice field under the other statutes. I believe that is the area of primary interest at this meeting.

Chief Weapons of FTC

Sections 5 and 12 of the FTC Act are the chief weapons by which the Commission endeavors to prevent (1) unfair methods of competition between business concerns and (2) unfairness to, or deception of, the public by businessmen.

As originally written, Section 5 of the FTC Act prohibited only "unfair methods of competition in commerce." The United States Supreme Court, in the first *Raladam* case,[1] held that corrective action must be based on the effects promotional methods had on competition, that effects of such methods on other elements of the public were not considered by the statute. While most promotional practices that were injurious to the general public could be and were disposed of under this limited grant of authority, some could not, and the development of cases under it was tedious and expensive. Consequently, in 1938, the Federal Trade Commission Act was given a general overhauling by what is commonly referred to as the Wheeler-Lea Amendment.[2] Section 5 was enlarged to also prohibit "unfair or deceptive acts or practices in commerce." This dispensed with the necessity of showing effects on competition. The *Bunte* case[3] held that the Commission was, under this section, granted authority to regulate practices in interstate commerce but was not given authority to regulate practices in intrastate commerce that substantially affected interstate commerce. Recently, the Commission issued a complaint charging, in effect, that dissemination of advertisements in interstate commerce for products sold and delivered over the counter constitutes commerce within the meaning of Section 5 of the FTC Act, and motion to dismiss by the respondent was denied.[4] If upheld, this will substantially lessen the burden in investigation and trial of many cases where it has been customary to show deliveries of merchandise or other related transactions across

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[1] *FTC v. Raladam Company*, CCH TRADE REGULATION REPORTS (Supp. Vol. VI) ¶ 5572, 283 U. S. 643 (1931).

[2] 52 Stat. 111 (1938); 15 USC Sec. 45 (1958).

[3] *FTC v. Bunte Brothers*, 1940-1943 TRADE CASES ¶ 56,098, 312 U. S. 349 (1941).

[4] *S. Klein Department Stores, Inc.*, Dkt. 7891.

state lines. When one considers that the Commission now has only 801 employees to discharge its vast responsibilities, the need for the Commission's utilizing all legitimate and proper efforts at economizing its staff's efforts is apparent.

Congress left to the Commission—a body of experts—the task of defining unfair methods of competition and unfair or deceptive acts or practices, based on continuing experience and intimate contact with the ever-changing phases of business endeavor. Human ingenuity, free and inspired by the profit motive, has been productive not only of immeasurable good but also of a myriad of ingenious, unethical plans of promotion. Congress could not anticipate all these unethical encumbrances and handicaps to a free capitalistic economy, so it empowered the Commission to proceed within the broad structure of Section 5 of the FTC Act to define and enjoin these methods and practices. I believe that a fair analysis of the history of the Commission forces even the most skeptical to concede that this was an excellent approach to the problem and that the Commission has not abused its prerogatives. I also believe that only a group which observes the continued impact of the various competitive practices employed by industry can fully and properly evaluate the importance of any one practice on industry.

Recent Deceptive Practices

Among the deceptive practices that have more recently received Commission attention under Section 5 of the FTC Act are "payola" and "plugola"; advance-fee and advance-loan rackets; vanity publishers; bait advertising and other rank misrepresentations in the home-improvement field (patios, porches, paints, siding materials, storm windows, jalousies, tile, shingles, etc.); gross misrepresentations as to price, financing, guarantees and terms of sale of secondhand cars, of re-refined used motor oil as new, of rebuilt automobile clutches and of television picture tubes with either no disclosure or inconspicuous disclosure of the fact that they have been rebuilt; passing off of foreign-made goods as preferred American goods; misrepresentations by a large segment of industry regarding terms of their guarantees; misrepresentations of the standing of correspondence schools, and facilities of, and opportunities for, employment derived from their offered courses; falsifying of profits, etc., to be derived from vending machines and other self-employment businesses; fic-

titious pricing; misrepresentations of size and composition of rugs and other commodities sold for household use; and misrepresentations of nursery products.

From an examination of this list it will be noted that most of the practices that are the subject of corrective action arise from advertising and labeling of merchandise. Section 5 of the FTC Act is so broad that it applies to all advertising, including labeling, of all products subject to Commission jurisdiction. Banks, common carriers and air carriers and, to a limited extent, packers and stockyards, and insurance to the extent it is regulated by the states are exempted from Commission jurisdiction. Labeling of food, drugs, devices and cosmetics are subject to Section 5 [5] but, by liaison agreement, the Commission restricts itself to advertising. The Food and Drug Administration, which has primary jurisdiction over labeling of these four classes of products, regulates labeling of them, thus avoiding duplication of effort.[6]

"Truth in Fabrics and Furs" Statutes

Experience in application of Section 5 of the FTC Act to textiles and furs demonstrated its inadequacy—that in this vital area of our economy ethical business and the consuming public were not receiving the protection they should receive against unethical business, which resulted in the enactment of the "truth in fabrics and furs" statutes. These are the Wool Products Labeling Act (1941), Fur Products Labeling Act (1952), Flammable Fabrics Act (1953) and Textile Fiber Products Identification Act (1958). The distinctive features of these laws are that they place specific responsibilities on manufacturers and other sellers of the products to make certain disclosures relative to composition, etc., of their products; they contain greater grants of jurisdiction under the commerce clause of the Constitution than was made under Section 5 of the FTC Act; they empower the Commission to issue rules and regulations that have the force of law, a power the Commission does not have under the FTC Act; and they afford the remedies of temporary injunction,

[5] *Fresh Grown Preserve Corporation v. FTC*, 1940-1943 TRADE CASES ¶ 56,191, 125 F. 2d 917 (CA-2, 1942), enf'd, CCH TRADE REGULATION REPORTS (Supp. 1941-1943) ¶ 53,003, 139 F. 2d 200 (CA-2, 1943).

[6] Adopted June 4, 1954; not published in *Federal Register* but made available to the press.

criminal prosecution in the United States District Courts, and seizure. A very substantial number of current deceptive-practices cases arise under these statutes. A staff of investigators and inspectors devote their entire time to investigating industry's observance of the requirements of these laws. This illustrates the fact that disregard of responsibilities under the free enterprise system generates more and tighter controls.

Section 12 of FTC Act

The Wheeler-Lea Amendment added Sections 12 through 16 to the Federal Trade Commission Act. Sections 12 through 15 relate only to advertising of foods, drugs, therapeutic devices, and cosmetics. Section 12 declares it unlawful to disseminate or cause the dissemination of false advertisements for these four classes of products:

(1) By United States mails, or in commerce by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase in commerce of food, drugs, devices, or cosmetics.

There has been no case where jurisdiction has been based solely on dissemination of an advertisement for a product subject to Section 12, through the United States mails, entirely within the boundaries of one state but it is believed that such an action is authorized by Section 12. It is clear that jurisdiction exists where the advertisement is disseminated in interstate commerce for the purpose of inducing, etc., intrastate purchases of foods, drugs, devices or cosmetics in interstate commerce.[7] Of course, the dissemination of such an advertisement in interstate commerce which may result in the purchase of one of these four types of products in interstate commerce is sufficient to establish jurisdiction under Section 12. The Wheeler-Lea Amendment made the FTC Act the broadest consumer protective statute thus far enacted. The vast majority of the approximately 2,200 cases now under investigation by the Commission's Bureau of Investigation and of the many matters under consideration by the Bureau of Consultation are under these sections. In these days when the medicine man sells not from the back of a truck, but from radio and television studios and through millions of printed adver-

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[7] *O-Jib-Wa Medicine Company*, Dkt. 6548, 53 F.T.C. 1205; *Renor Company, Inc., et al.*, Dkt. 6617, 53 F.T.C. 1222.

tisements in leading publications, direct mail, etc., it is particularly important that the Commission, which is charged with a primary responsibility in protecting the health and purse of the general public, be in position to move fast and with only the necessary minimum burden of proof as to jurisdiction.

As has been previously mentioned, the Commission has not been given authority to seek a temporary injunction or issue an interlocutory order to cease and desist for violations of Section 5. It may be of interest to call attention to the fact that some who have taken a special interest in the regulatory efforts of the Commission feel that such authority should not be granted under Section 5 to cope with current promotional methods. They urge that the "truth in fabrics and furs" statutes relate to products that are no more vital to public welfare than are those covered only by Section 5 and that those statutes already have injunctions, seizure and criminal provisions.

Sections 13 and 14

To the formal remedy provided in the original statute—the complaint and order to cease and desist—there was added, by Section 13, the provision that where it appeared in the interest of the public, the Commission might bring suit in a United States District Court for a temporary injunction against the dissemination of false advertisements for foods, drugs, therapeutic devices and cosmetics. This remedy has been used in a considerable number of cases involving dangerous drugs [8] and two instances where the injury was essentially economic.[9] Section 14 of the Wheeler-Lea Amendment also provided a third remedy, that of criminal prosecution in the United States District Court where the false advertisement is for a food, drug, therapeutic device, or cosmetic, and its use may be injurious to health or if the violation is with intent to defraud or mislead. Only two cases have been brought under this section.[10]

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[8] *FTC v. Benham*, 3 F.T.C. S&D 642 (DC Ill., 1939); *FTC v. Kaplan*, 3 F.T.C. S&D 656 (DC Ill., 1939); *FTC v. Sekov Corporation*, 3 F.T.C. S&D 669 (DC Calif., 1940); *FTC v. Caplan*, 3 F.T.C. S&D 699 (DC Va., 1940); *FTC v. Allied Pharmacal Company, Inc.*, 3 F.T.C. S&D 704 (DC Ohio, 1940); *FTC v. Miller*, 3 F.T.C. S&D 706 (DC N. Y., 1940).

[9] *FTC v. Rhodes Pharmacal Company*, 1950-1951 TRADE CASES ¶ 62,894, 191 F. 2d 744 (CA-7, 1951); *FTC v. National Health Aids*, 108 F. Supp. 340 (DC Md., 1952).

[10] *U. S. v. Petric*, 3 F.T.C S&D 723 (DC Ill., 1939); *U. S. v. Rhodes Pharmacal Company*, 5 F.T.C. S&D 801 (DC Pa., 1951).

As a result of the passage of the Wheeler-Lea Amendment and the Federal Food, Drug, and Cosmetic Act of 1938, over-the-counter sales of dangerous drugs, therapeutic devices, and cosmetics have been practically eliminated. Also, during the past two decades the formulation of proprietary preparations has been greatly improved. If appealing claims were made under these laws, the best formulas had to be used in making the drug products offered. Although the Commission has not very often employed these extraordinary remedies, they have had a most wholesome influence in affected industries. It is likely that economic injury more often will be the basis of their use—especially Section 13—in the future.

In the food and drug area, attention has especially been given, during the past few months, to the requiring of disclosures by promoters of antibiotics that milk from dairy cattle to which those antibiotics had been administered should not be used or sold for human consumption for a specified time after use; to false claims in advertisements for so-called "health books"; to misrepresentations for contact lenses, arthritic preparations, vibrating devices alleged to control weight and body dimensions, and vitamins; and to quality control of drugs.

Regulation of Advertising Essential

Honest advertising is a vital part of our dynamic economy. It stimulates demand for new and better goods, which in turn encourages new inventions and scientific research. Honest advertising sharpens competition by permitting comparisons in utility and price. These factors are reflected in greater employment and greater purchasing power, which enables us to consume our ever-increasing production. This is a healthy cycle, but false advertising is a poison in the life blood of a free economy. False and misleading advertising is an unfair method of competition, for it forces other businessmen to adopt practices that are against their ethical standards or to lose their businesses. Also, it is decidedly unfair to the consumer, for it enables the false advertiser to secure money from the consumer that he would not otherwise obtain. It diverts demand from better merchandise to less desirable, which distorts the free working of supply and demand, the most basic of the economic laws. In the area of foods, drugs, therapeutic devices and cosmetics, false advertising not only presents all these economic factors but sometimes

poses health hazards of substantial importance. Consequently, regulation of advertising is a very essential task. During the approximately 25 years I have spent in very close association with the Commission's regulatory work in that field, I have seen no time in which there has been such a strong reaction by the consuming public, registered directly and through consumer protective groups, to advertising practices. In addition to the many corrective actions initiated by the Commission staff, an increasing number of which involve entire industries, some 7,000 informal complaints were received by the Commission last year. Some of those also related to practices quite common in entire industries. Incidentally, it might be of interest to you and your clients to know that there is an increasing number of complaints about bad taste in advertising (a matter of importance, but not controlled by any laws administered by FTC). The attention given to false advertising by Congressional committees is, of course, known to you. I mention these factors because much advertising that is the basis of corrective action has been drawn by advertising agents and approved by counsel.

One of the recent modifications in policy has been a determination of the role of the advertising agent and his inclusion in false-advertising investigations. I think you can expect more advertising agents to be joined in all forms of corrective actions in the future.

The doctrine of *caveat emptor,* which came into our law from England,[11] is old but it is not honored for its antiquity. As late as 1900, a United States Circuit Court of Appeals denied injunctive relief to a manufacturer of aluminum washboards against a competitor who used the word "aluminium" on washboards devoid of aluminium, stating that: "if . . . all persons [are] compelled to deal solely in goods which are exactly what they are represented to be, the remedy must come from the legislature, and not from the courts." [12] In the area of trade regulated by the Commission the doctrine of *caveat emptor* is now legally dead. But that is nothing to be alarmed over because it only means that those who enjoy the freedoms of our economy must also bear concomitant responsibilities and that when they advertise their merchandise, they must convey

[11] In 1603 a British court held that when a vendor stated that "this is a Bezor stone" (supposed to have therapeutic efficacy), there was no cause of action because the statement was legitimate puffing (Exchequer Chambers Cro. Jac. 4).

[12] *American Washboard Company v. Saginaw Manufacturing Company,* 103 F. 281, 285 (CA-6).

only truthful impressions. This is about all the law one needs to know to avoid violation of the provisions of the FTC Act against false advertising unless he wishes to gamble in the gray area. On the other hand, the facts are often involved and complicated.

Relationships with Other Agencies

It has been my pleasure and responsibility under the general supervision of the Commission's secretary, to maintain our liaison relations with most other government agencies for the past several years. During that time closer relationships have been established with agencies administering related statutes. One of these agencies is the Federal Communications Commission. We have, since February 21, 1957, been furnishing that agency with copies of every stipulation and order entered where radio or television advertisements have been a basis of corrective action and with the identity of the stations broadcasting the advertisements, for their use in considering whether those stations are conducting their operation in conformity with statutes administered by the Federal Communications Commission.[13]

There has been a striking change in the volume, media and format of advertising since the Commission was empowered to regulate advertising. In 1914 advertising budgets were small and advertisements were brief and their format simple; there was only printed media, and newspaper and magazine circulations were comparatively small. Now $11.5 to $12 billion are spent annually in advertising; radio and television have come into use to the point where radio can be heard anywhere in the country from several stations and over 95 per cent of the country can receive television broadcasts. Seventeen hundred newspapers distribute about 57.5 million newspapers daily, 270 general and farm magazines have a circulation of about 183.5 million, and direct mail advertising exceeds 1.5 billion annually. To further complicate the matter much advertising relies upon inferences and overtones to create impressions desired by the advertiser and many scientific near miracles in the medical field and other fields of learning have created an atmosphere in which even the impossible can be made to impress the mind as plausible. That, however, presents not an impossible task in regulation, but only an interesting challenge. Two basic principles that often go through my mind

[13] 22 *Federal Register* 2318 (April 6, 1957).

when considering advertising material are that the law does not equate adroit deception with truth and that, given the inclination, one can easily employ our very flexible language to state the whole truth. Another is that the reader is under no duty to search for hidden meanings or small-print qualifications.

These enormous changes and growth in business have necessitated constant re-evaluation of, and modifications and adaptations in, the Commission's formal and informal procedures and emphasis in expenditures of its resources. In this connection, the Commission has the benefit of not only its management personnel but, through a well-managed incentive awards program, suggestions from all of its employees. In the past few years it has had one extensive survey by a well-recognized, privately operated management group and periodic assistance by other arms of the federal government interested in efficiency. Out of this have come consent-order procedures (employed in about 84 per cent of our formal cases); enlargement of facilities for monitoring all forms of advertising; increased use of Section 6 (FTC Act) investigations; new forms and increased use of industry-wide educational and enforcement programs; and innumerable small changes that have modified procedures or have eliminated unnecessary ones. Time does not permit me to extend this thought further than to express my opinion that, under very able leadership, the morale of the Commission's staff and its total product are at an all-time high.

Devising Methods of Testing Products to Determine Propriety of Advertising Claims

One of my prime responsibilities for many years has been to assist in devising methods of testing various products to determine the propriety of questionable advertising claims made for them. Normally, scientific research is conducted for the purpose of learning basic principles or to adapt those principles to practical use. While knowledge acquired by this method solves most of the scientific problems involved in questioned advertising, sometimes it is inadequate. The advertiser whose claims are questioned may not have looked for a scientifically proved principle but, I sometimes suspect, has found a scientifically unexplored area or unresolved principle on which to base his advertising theme. Where the public interest is sufficient, the Commission's staff must devise tests which, coupled

with what is already known scientifically, will be sufficient to resolve the propriety of those claims.

The foundation step in this type of investigation is to determine the meaning of the exact advertising claim under consideration and whether it may have the tendency and capacity to deceive a substantial segment of the public. The language of the questioned advertisement usually provides the answers to these two questions. However, if it does not, a consumer survey is conducted. If the advertisement does create impressions that may be false, a proper sample must be acquired, adequately identified, and delivered to the scientist who is to perform the tests.

As to the tests, first, they must be properly conceived—that is to say, they must be conducted in such a manner that the results thereof definitely can be attributed to use of the product in question when used according to directions or, in the absence of specific directions, when used under customary or usual conditions. Other factors that may appreciably affect the results must be eliminated. There must be a sufficient number of tests, on a sufficiently large and representative sample, that the results reflect the general behavior pattern of the product.

Second, the tests must be properly executed. Care must be taken that the planned procedure is exactly performed and that no variable factors are permitted to be introduced. Test results must be accurately read and fully recorded. Shop notes must be preserved.

Third, results of the tests must be critically examined to determine what firm conclusions can rest on them.

The final question is whether (if the claims appear false) these tests, coupled with available general scientific knowledge that can be furnished by experts, enable the Commission's staff to maintain the requisite burden of proof. Need for conducting such tests is increasing annually.

Perhaps you have noted our recent attacks on demonstrations and tests.[14] Man's experience has conditioned his mind so that he is

[14] *Hutchinson Chemical Company*, Dkt. 7140; *Libbey-Owens-Ford Glass Company et al.*, Dkt. 7643; *Colgate-Palmolive Company*, Dkts. 7736 and 7660; *Brown & Williamson Tobacco Corporation et al.*, Dkt. 7688; *Aluminum Company of America*, Dkt. 7735; *Standard Brands, Inc.*, Dkt. 7737; *Lever Brothers Company et al.*, Dkt. 7747; *Carter Products, Inc.*, Dkt. 7943; *American Chicle Company*, Dkt. 6791.

inclined to accept visual demonstrations with less skepticism than as to what he reads or hears—hence the old axiom that "seeing is believing." There is, I believe, nothing new in principle involved in these cases, but an adaptation of old principles to new circumstances. Generally speaking, these attacks are based on advertising representations that certain tests, which are visually illustrated, prove that the advertiser's product possesses certain desirable attributes when those tests do not so prove. I think that if a demonstration creates a false impression about a material fact—a fact that is likely to incline the viewer to buy the promoter's product or to dissuade him from a competing product—it is actionable under the FTC Act. These cases show that the falsity of the test may, under some circumstances, be questioned without going broadly into the merits of the product. It is sufficient if the tests are false and they relate to a material fact. If you will refer back to my discussion of how tests are conducted to resolve the truth or falsity of an advertising claim regarding the performance of a product, you will see that proof by tests sometimes is not an easy, quick and dramatic procedure and that the advertiser who employs this method often assumes a very considerable burden. Prevalence of advertising involving this theme suggests it will receive increased attention.

Section 15 of the FTC Act has recently received increased attention. The major portion of this section defines "foods," "drugs," "devices" and "cosmetics" and also states a rule for construing advertisements for these four classes of products. However, that was not a new rule, for it had already been in use for many years in construing advertisements under Section 5.[15] Section 15 states this rule of construction as follows:

> . . . in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combination thereof but also the extent to which the advertisement fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement or under such conditions as are customary or usual.

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[15] *FTC v. Royal Baking Powder Company*, CCH TRADE REGULATION REPORTS (Supp. Vol. V) ¶ 5523, 281 F. 744 (CA-2, 1922); *Haskelite Manufacturing Corporation v. FTC*, 1940-1943 TRADE CASES ¶ 56,317, 127 F. 2d 765 (CA-7, 1942); examples of more recent cases are *Modern Hat Works*, 28 F.T.C. 545 (1941) and *Adell Chemical Company, Inc.*, 54 F.T.C. 1801.

The only qualification to this broad coverage is medical advertising of drugs which is disseminated only to members of the medical profession and which "contains no false representation of a material fact" and is accompanied by a quantitative statement of the formula of the product. The full meaning of this qualification has not been resolved. However, it has accounted for a very limited amount of regulation of advertising to physicians. In 1938, when this amendment was enacted, the probability of deception of the profession about the beneficial and side effects and contraindications of the drugs then in use was slight. In the recent past the introduction of a large number of new drugs that are so potent they greatly influence basic bodily processes, coupled with greatly stepped-up advertising programs to physicians and substantial modifications in methods of presentation in such advertisements have caused some to conclude that now even physicians may be deceived by entrepreneurs of the so-called ethical drugs. Those of this persuasion contend that the average busy physician does not have time to acquaint himself with the basic literature available on these new drugs and that advertising to physicians should receive closer scrutiny by the Commission, especially where such advertisements do not acquaint the physician with the negative aspects of such drugs. Consequently, those of the Commission's staff most concerned with this problem have recently given much thought to that qualification, to current conditions in drug advertising to the medical profession and to the possible need for modifications of this part of the statute to adequately equip the Commission to regulate that form of advertising.

Inquiry is sometimes made as to what the future holds so far as possible extension of regulations in the area of deceptive practices is concerned. Businessmen and their advertising agents and their counsel hold the answer to this question, for they exercise the creative role in business promotional methods and they bear the responsibilities of maintaining the credibility level of advertising and good reputation in industry and before the public. The underlying principle involved was well stated by Edmund Burke over 160 years ago, as follows:

> Society cannot exist unless a controlling power upon will and appetite be placed somewhere; and the less of it there is within, the more there must be without. . . . It is ordained in the eternal constitution of things that men of intemperate minds cannot be free. . . . Their passions forge their fetters.

[The End]

The Role of the Men of Science and Lawyers in Lawgiving

By KENNETH E. MULFORD

This Paper Was Presented at the January, 1961 Meeting of the New York State Bar Association. The Author Is Assistant to the Executive Vice President, Atlas Powder Company, Wilmington, Delaware.

THE MIRACLES OF SCIENCE and modern technology are all around us—in the foods we eat, in the planes that brought some of you to this meeting, in our recreation-room television set, in the synthetic fabrics we wear, in life-saving drugs, in satellites that circle in outer space. Many of these are part of our daily life, yet only an infinitesimal few of us have been educated in the scientific disciplines necessary for even a meager understanding of how these miracles are possible. Nor is it reasonable to assume that most of us will understand how many of these things came about. No matter how proficient or knowledgeable we may be in our own fields of activity, most of us are living through an era of breath-taking developments, ignorant of the scientific principles that lie behind them.

For example, I was given a pocket-size transistor radio for Christmas. Its reception is truly remarkable. But I am told that if used on an airplane it may interfere with some phase of modern navigation equipment. I know nothing of the whys or wherefores, but obviously my decision is not to use it on a plane. If someone announced that persons carrying a gadget such as this might ultimately contract some horrible, incurable disease, I would be somewhat skeptical, but I would have no more basis for reaching a conclusion than I have about its effect on the plane.

In the absence of some authoritative statement by some knowledgeable person or group in whom I have confidence, there exists in each case a tendency toward some degree of credence because of lack

of personal knowledge; because of fear and because of normal protective instinct. How many times we have heard the adage "better to be safe than sorry." Unfortunately, this provides an opportunity for those who, out of either ignorance or selfish motives, wish to engender fear and public apprehension about many of the new developments of science.

This does not mean that fear which frequently associates itself with acts of courage is to be condemned. As has been said in *The Great Ideas*, we should strive for "prudence to decide what things should be feared, when they should be feared, and how much; and so a prudent judgment is involved in fearing the right things at the right time and in the right manner—neither too much nor too little."

The fears that surround us and our protective instincts are prime movers in the development of laws of human conduct. If we accept the fact that the expressions and attitudes of the general public influence our lawgivers in patterning new laws or modifying old ones to deal with the scientific revolution of our age, it becomes obvious that our scientists must play an ever-increasing role, directly or indirectly, in lawmaking. Much of what our government does—whether in connection with regulation of foods, drugs and cosmetics, sprays and insecticides, with air-pollution control programs, or in deciding what fields of scientific and medical research should be encouraged with grants—has a direct bearing on the rate and direction of scientific progress.

If we are to have progress, alleviation of unjustified fears and alarms becomes as important as the timely development of protective measures. This creates for those of us in law, no less than for those in science, a problem of communications: How can we help millions of people to make "a prudent judgment in fearing the right things at the right time" or, conversely, of not fearing those things that need not be feared? How can we help our lawmakers reach sound decisions that will, on the one hand, protect the public interest and, on the other, facilitate scientific and technological progress?

There are no simple answers, no pat formulas to meet this challenge of communications. Some progress, in the field with which I am best acquainted, food additives, has been made in recent years, although much remains to be done. As you know, the Food Protection Committee of the National Research Council has made commendable strides in analyzing some of the questions raised about food additives, and in publishing documents based upon sound scientific judgment.

To the extent that they are covered adequately in the general press and reach those who influence the public in health matters, they can help to lessen unjustified fears and provide Congress with useful guidelines for drafting constructive legislation.

Last year the Manufacturing Chemists' Association and the Nutrition Foundation cooperated in carrying out an educational program, on food additives, to reach home economists, nutritionists and dietitians, home demonstration agents, public health leaders, food editors, writers and librarians. The association is following this up with a continuing effort to reach the same audiences. Food and Drug Administration officials have done much, through speeches around the country, to underscore the importance of chemicals in agricultural production and additives in modern processed foods.

It is heartening, too, to note the recognition given to the importance of early detection of public relations problems that may arise from new scientific developments by the Committee on Science in the Promotion of Human Welfare of the American Association for the Advancement of Science. To those of you who have not had an opportunity to read this report, I refer you to page 68 of the July 8, 1960 issue of *Science*. It rejects the view that scientists should follow a passive advisory role to government and, instead, urges that in dealing with social issues "the scientific community must demonstrate its responsibility" and "ought to assume, on its own initiative, an independent and active information role."

However, in studying the recommendations of the AAAS Committee, and the work of such groups as the National Research Council and the President's Scientific Advisory Committee, it seems to me that in the field of legislative assistance the scientists are confronted with serious difficulties.

The first of these arises out of the basic division of law into scientific laws and laws of human conduct. There is, of course, a fundamental difference between them. Scientific laws simply exist to be discovered and are inviolable. Newton had no choice as to what the laws of gravity should be. Neither you nor I nor the scientist can violate them nor can we change them. Consequently, when dealing with laws of their own disciplines, the scientists are not confronted with a decision of choice or selection as to how the law should be framed to be of the greatest benefit to society. This does not mean, of course, that the scientists are not confronted frequently with con-

flicting evaluations of scientific data that make it difficult to advise on the framing of human laws. Laws of human conduct are a matter of choice, differing in different lands and changing with social progress. Matters of choice involve alternatives. Furthermore, when alternatives are proposed in written form, there is the practical question: "What exactly do they mean?"

Earlier I pointed out that most of us must rely on the advice of competent scientists if we are to avoid false fears. However, there is the other side of the coin. Just as the public, lawyers and lawmakers need the advice of scientists, so also do the public, scientists and lawmakers need the advice of lawyers. Most scientists are naturally reluctant to participate in the drafting or interpretation of newly proposed laws of human conduct even though they may be necessary because of new scientific developments.

Thus, in last year's hearings on the color additive amendments, the House Interstate and Foreign Commerce Committee requested President Bronk, of the National Academy of Sciences, to name a panel of experts qualified to discuss the scientific problems arising from the cancer clause. A panel of some 13 distinguished scientists participated, with many urging some modification of the Delaney Clause. One of the scientists, while being questioned by a committee member, suddenly turned to the presiding officer—who happened, at that point, to be Representative Flynt of Georgia—and asked: "Would it be possible for the chairman of the committee to give the members of the panel . . . an official interpretation of the Delaney clause?"

To this, Representative Flynt replied candidly that it was "impossible to give a definitive answer," pointing out that this particular section of the law "is capable of as many different interpretations as there are members of a committee or panel." The scientists, therefore, were in the unhappy position of trying to make recommendations without any interpretation of the clause. Similarly, in the Kistiakowsky Committee report on the cancer proviso, I also detected a reluctance to interpret the clause, even though the committee had legal counsel.

A very important part of the job of communications is trying to understand the problems and the points of view of those with whom you are trying to communicate. Along with some other members of this group, I have been disappointed with certain sections of recent food and drug legislation. It is easy to say that those parts we do not like or agree with are simply the unfortunate result of Congress' play-

ing politics, in the sense of responding to what we believe are unjustified public fears. I suggest, however, that this is a gross oversimplification of our problem and that there is little to be gained in trying to make a scapegoat out of politics. In fairness, it must be remembered that members of the House and Senate committees face a difficult problem in drafting food, drug and cosmetic legislation. It is, I believe, to the credit of the House Commerce Committe that during important hearings on the use of polio vaccine in 1955, food additives in 1958 and color additives last year it called upon Dr. Bronk to choose panels of experts. As previously indicated, it is believed that these panels could be much more effective if they received sound briefings on the meaning of the legislation under consideration.

Even the use of a panel, however, does not free members of Congress from having to make difficult decisions. Congressmen are often in the position of having to weigh conflicting scientific judgments and, with few exceptions, to weigh them as laymen without benefit of scientific training. In 1955, for instance, two of the panel members called for a halt in polio inoculations, contending that the Salk vaccine at that time was too dangerous for use. Last year, a minority of another panel called for retention of the Delaney Clause without change.

The best that we can hope for, it seems to me, is that Congress will follow its own admonition to the Secretary of Health, Education, and Welfare in the food additives amendment to make findings of fact and base orders upon a "fair evaluation of the entire record" rather than merely upon "substantial evidence" in one direction.

In 1955, when introducing the panel of polio experts, the late Chairman of the House Commerce Committee, Representative Priest of Tennessee, commented:

> I believe that if properly informed the American people are able to come to wise conclusions, even admitting that among scientists, as all of us know, there are areas of controversy and differences of opinion.

All of us, I believe, have a part to play in this job of informing the people. Lawyers, as I have said, can help scientists by giving the best possible legal opinion—and that is not always easy—on what legislation may mean, so that scientists will have a better basis for making public policy recommendations. Surely, if the American Association for the Advancement of Science and similar groups are willing to undertake this work as a public service, we in the bar associations should be willing to work with them. **[The End]**

Foreign Law Comment

By JULIUS G. ZIMMERMAN

Chapter IV of the Latin-American Food Code Deals with Its Application to Containers of All Kinds. The Chapter Was Translated from the Original Spanish by Ann M. Wolf, of New York, Under Dr. Zimmerman's Supervision.

The Latin-American Food Code
Chapter IV

UTENSILS, RECEPTACLES, CONTAINERS, WRAPPERS, MACHINERY, AND ACCESSORIES

Article 51—All utensils, receptacles, containers, wrappers, machinery parts, pipelines, and accessories that come into contact with foods must at all times be in perfect hygienic condition, be made of or coated with materials impervious to the product, and not yield harmful substances or substances capable of contaminating or altering the organoleptic characteristics of the food. These requirements apply also to inside linings, which must be unbroken and continuous and impervious to the products used to sterilize them.

The use of the following materials shall be permitted without first obtaining an authorization:

1. Stainless steel, steel, cast iron, which may or may not be coated with technically pure tin, and chromium-plated iron;

2. Copper, brass, or bronze, lined with a coating of technically pure gold, silver, nickel, chromium, or tin. This lining shall not be required for boilers, vessels, and kettles used to cook candy and sugar syrups, for mortars, pans of balances, and weights;

3. Technically pure tin, nickel, chromium, or other metals, or alloys thereof with harmless metals;

4. Virgin tin plate;

5. Tiled or enamelled iron which, when exposed to acids, does not yield lead or other harmful compounds, provided that it is kept in a good condition of preservation;

6. Ceramic materials, baked clay glazed on the inner side which, when exposed to acids, do not yield lead or other harmful compounds, glass, crystal, marble, and nonodorous woods;

7. Pasteboard, cardboard, paper, or substitutes therefor, vegetable or animal fiber cloths, which may or may not be waterproofed;

8. Paper coated with wax, stearin or paraffin, and parchment or parchment-like paper, free from boric acid, formic acid, or other preservatives (particularly in the case of dairy products), paper impregnated with 20%* of a nonodorous mineral oil (only to wrap fruit);

9. Pulp prepared with a base of various flours, fatty materials, mineral salts, and other substances the use of which is permitted. For the manufacture of ice cream containers, up to 0.5 grams of borax may be added to each kilogram of pulp or board;

10. Gum or rubber or substitutes therefor, free from harmful metals and toxic substances in general;

11. Plastics free from harmful substances;

12. Cloths made of vegetable or animal fiber, either plain or waterproofed with harmless substances. When used for hams and sowbelly, these cloths may be coated with petroleum tar; the use of coal tar or other tars which have a phenol or anthracene reaction or an acid or alkaline reaction is prohibited;

13. Such other materials as the health authorities may approve.

The use of galvanized iron or zinc-plated iron is generally prohibited in containers which come into contact with foods or raw materials for foods, except at meat markets. The food industry shall be granted a term of ten years from the date of promulgation hereof within which to replace this material, and thereafter establishments preparing or handling food products shall be prohibited from using machines or utensils containing it.

Article 52—Metals and other materials which come into contact with foods are not permitted to contain more than 1% of lead, antimony, zinc, copper, or other impurities, or more than 0.05% of arsenic or other substances which the health authorities consider harmful.

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*Note of the translator: By weight.

Tin-plated surfaces which come into contact with foods shall have a nominal tin content of at least 0.50 by weight in BB units. Excepted herefrom are the metal fittings of siphons, for which particular requirements are fixed in another part of this Code.

The use of tin plate with a nominal tin content of at least 0.25 by weight in BB units shall be permitted to can liquids when the inner surface is coated with a protective varnish. The use of tin plate with a nominal tin content of at least 0.14 by weight in BB units, or of a plain black plate coated with protective varnishes shall be permitted to pack powders or relatively dry products.

All enamelled, lacquered, or varnished materials must have a surface covered completely in accordance with the best technological practice suitable for the product to be packed and must not contain lead, antimony, or any other element or compound considered harmful on the basis of tests to be conducted in accordance with regulations to be issued.

Article 53—Whenever this is considered necessary, the inside of metal containers may be protected with varnishes, lacquers, enamels, or other coatings or protective treatments that meet the requirements of this Code.

Only the following substances may be present in varnishes and plastics intended to be in contact with foods:

a. Natural or synthetic resins and/or insoluable polymers which do not react to foods;

b. Solvents having a boiling point of less than 150° C., or other solvents the elimination of which in the finished product is assured;

c. Plasticizers: paraffin oil, castor oil, glycerine, diethylene glycol, triethylene glycol, propylene glycol, stearates and ricinoleates of ethyl, butyl, amyl, and non-toxic metals such as calcium;

d. Hardeners: hexamethylenetetramine;

e. Antioxidants and stabilizers: cobalt and manganese resinates;

f. Pigments: colors authorized by this Code;

g. Improving agents or fillers: talcum, mica, titanium oxide, sawdust, siliceous earth, and other inert bodies the use of which is permitted;

h. Other materials specifically authorized by the health authorities;

i. Moreover, the varnishes and plastic materials must react satisfactorily to corrosion tests made with acids, alkalis, fatty bodies, and

hydrogen sulfide and to aging tests conducted with fish preserved in oil, canned tomato juice, vegetables, and salted meats, depending upon the use for which they are intended.

Article 54—For the painting, decorating, and enamelling of the containers, domestic, commercial, or industrial utensils and other materials mentioned in the preceding articles, only harmless colors may be used; the use of dyes containing antimony, arsenic, barium, cadmium, copper, chromium, mercury, lead, uranium, and zinc in soluble forms is prohibited.

Article 55—The varnishes sold to protect the inside of tanks for drinking water must be impervious to potable water and chlorinated water and are not permitted to contain: antimony, arsenic, barium, copper, mercury, lead, zinc, or cobalt in a proportion exceeding 1% by weight.

Article 56—The inside weldings of containers, utensils, and accessories which come into contact with foods must consist of tin that contains not more than 1% of lead or other impurities and not more than 0.01% of arsenic. The outside weldings may contain any percentage of lead.

Article 57—The canning industry shall use preferably mechanical closures (rivets); the rubber or rubber substitute seals used may contain talcum, chalk, magnesium, and other harmless products, but must seal the cans hermetically without breaks in the continuity.

Article 58—Containers may be closed with the following materials:

1. Technically pure tin, except for cans for evaporated milk and similar products which, to permit the sealing of the pouring perforations, may be welded with tin lead;

2. Virgin cork and cork substitutes (polyethelene, etc.);

3. Rubber and rubber substitutes free from harmful substances;

4. Metal, tin-coated, varnished, enamelled or ceramic caps mounted on rings made of cork, rubber, or substitutes therefor which are free from harmful substances;

5. Metal caps (crown corks) which have on their inside a disk of cork, aluminum, or technically pure tin;

6. Glass, porcelain or such other materials as the competent health authority may approve.

Article 59—Industrialists, merchants, or representatives are strictly prohibited from using receptacles or containers which bear legends or

trademarks belonging to other products that circulate on the market or which were previously used for products not coming from the manufacturer or merchant who uses them, with the special exceptions fixed in this Code. Such receptacles and containers, as well as containers with a chipped neck shall be confiscated immediately.

Article 60—The air in containers may be replaced by an inert gas, such as nitrogen, carbon dioxide, or others permitted by the competent authority. This operation need not be declared in the labeling.

Article 61—Returned containers may be re-used, provided that they can be sterilized properly before re-use. Such containers must be perfectly clean, and they must be disposed of when, due to prolonged use, they are oxidated, stained, or deformed, or when they can no longer be identified properly.

Article 62—Foods are prohibited from being manufactured, held, and sold if they are in direct contact with:

1. Printed paper;

2. Used or stained paper;

3. Paper containing harmful products, or products the use of which is prohibited, such as: plaster, alum, baryta, bakelite and synthetic resins, coal tar and anthracene derivatives, aniline dyes not permitted by the competent health authority, unauthorized preservatives, etc.;

4. Papers colored with vegetable or synthetic dyes the use of which is permitted, which rub off easily, however;

5. Lead paper or tin foil containing more than 1% of lead or antimony and more than 0.01% of arsenic;

6. Cardboard, paper, cork, and substitutes therefor which are not of virgin grade.

Any products which violate this article shall be considered unsuitable for consumption and shall be confiscated immediately, without prejudice to the imposition of the respective penalty.

Article 63—Food products exhibited for sale or shipped for sale to the public must be protected from every possible contamination (dust, mud, insects, etc.); foods not packed may be handled only by authorized personnel in possession of health certificates. Any paper in direct contact with foods must be virgin grade paper and comply with the requirements of the preceding article.

Article 64—Lead or tin foil containing too much lead and papers dyed with aniline dyes which are considered harmful, but do not rub off easily may be used, provided that a sheet of white or waterproof paper, as the case may be, is placed between them and the food.

Article 65—In wrappers for sausages, chocolate, bonbons, hard candy, etc. the tin or aluminum foil may be replaced by colorless cellophane, emerosin, cephalin, pure cellulose film, and similar products, and other authorized substances.

Article 66—Receptacles which originally or at some time have been in contact with products other than foods, or which are incompatible with foods are prohibited from being used for food products. Moreover, food and beverage receptacles are prohibited from being sealed with used caps. Industrial products are prohibited from being packed in food receptacles.

Article 67—Granulated metals, small shot or bird shot used to clean receptacles and containers intended for foods, beverages and raw materials used therein must be free from lead, arsenic, and other toxic substances.

Article 68—Sponges and metal pads used to clean glasses and receptacles intended for foods and beverages are not permitted to be manufactured with copper, zinc, or alloys of these two metals, or with iron or other metals coated with copper, tin, zinc, or lead.

Article 69—Containers, utensils, and other elements which come into contact with foods may be disinfected only with chemicals that cannot affect the foods or produce toxic effects. After disinfection they must be properly rinsed with large amounts of potable water that must not contain more than 5 to 10 p.p.m. of active chlorine, or steamed.

Article 70—At confectionery shops, bars, hotels, restaurants, eating houses, hostelries, beverage outlets, dairies, cafeterias, and similar establishments, the dishes, silverware, plates, cups, glasses, and goblets must first be washed under running water and then for two minutes be disinfected with boiling water and/or steam, or immersed for at least twenty seconds in a solution containing 60 p.p.m. of free chloride. The sterilization may be effected by way of any authorized chemical or physical method. Where glasses, goblets, and cups are not sterilized, the use of hygienic paper cups is compulsory.

Dishes, plates, cups, glasses, and goblets which are cracked or have chipped rims are not permitted to be used and must be destroyed. The use of wooden plates, jars, and cups is prohibited.

Report on the Sixth Symposium on Foreign Matters in Foods

By ERNST ABRAMSON, M.D.

THE SIXTH SYMPOSIUM on Foreign Matters in Foods was held at the National Institute of Agriculture in Madrid, Spain, from October 10 to 15, 1960. The participants numbered some 200 persons, most of them coming from Europe. There were, however, also participants from Canada, Japan and the United States of America.

The purpose of this symposium was to study various problems arising from the intentional or unintentional addition of "foreign matters" to foods intended for people or animals and to promote all activity necessary to guarantee the hygiene and wholesomeness of foods. Another aim of the symposium was to discuss the hygiene and the nutritive value of foods and the possible inconveniences to public health caused by intentional or unintentional additives in foods and to establish principles for a rational protection of the quality and hygiene of foods. Finally, it was the purpose of the meetings to promote the elaboration of a Codex Alimentarius Europaeus.

The symposium in Madrid was divided into six parts. In the first part, bacterial processes were discussed. Professor A. Barret of Versailles, France, reported on the bacteriological fermentation of some vegetable substances with regard to the preparation of foods, their nutritive value and the possibility of preserving them. Professor E. Brochu of Oka-La Trappe, Canada, spoke on fermented milks from the point of view of their vitamins as well as their hygienic and nutritive value. Dr. B. P. Eddy of Cambridge, England, reported on the relationship between nitrite and bacteria in the manufacture of bacon. Vitamin-producing bacteria were discussed by Professor Santa Maria of Madrid. Mrs. Marta Blinc of Yugoslavia talked about acid-forming bacteria in the fermentation of bread and their influence on its quality. Professor C. Antoniani of Milan, Italy, discussed acetobacter aceti as a valuable source of enzymes, and Dr. H. J. Rehm of Munich, Germany, lectured on the transformation of sorbic acid in foods.

The second part of the symposium dealt with processes started by fungi. After an introductory report by Professor J. Jacquet of Caen, France, on the maturing of cheese and other milk products,

Professor G. Mackinney of Berkeley, California, among others, spoke on the synthesis of caretenoids by fungi. In addition, the formation and presence of antibiotics in foods were discussed.

The third part of the symposium dealt with the importance of yeasts. Professor J. M. Xandri Taguena of Madrid gave a report on the part played by yeasts in the development of the aroma and bouquet in alcoholic beverages, and Professor J. Baraud talked on the formation of higher alcohols and fatty acids in alcoholic fermentation. A lecture by Professor W. Grab of Giessen, Germany, covered the toxicology of some products of alcoholic fermentation, and a lecture by Professor Fabriani of Rome, Italy, discussed yeasts in bakeries.

As a fourth part of the symposium, questions were discussed pertaining to processes started by enzymes. In this connection it may be mentioned that Professor G. Mocquot of Jouyen-Josas, France, spoke on the coagulation of milk by rennet, Professor J. Hollo of Budapest, Hungary, reported on the correlation between the enzymatic decompositions and the staleness of starch in bread, and Professor R. Grau of Kulmbach, Germany, discussed the biochemical processes during the maturing of meat. Professor A. Goded y Mur of Saragossa, Spain, reported on the enzymatic transformation of fats, particularly in milk products. Professor M. Flanzy of Narbonne, France, discussed the biological, toxicological and analytical aspects of methyl alcohol in wines and clarified fruit juices, and Professor A. Bertuzzi of Milan, Italy, spoke on how to reduce the methyl alcohol content in alcoholic beverages. Mr. W. Spoon of Bussum, Holland, talked on enzymes and their activity in developing flavour and colour of tea, cocoa and coffee, and Professor G. Mackinney discussed the enzymatic changes in chlorophyll as a result of processing.

In the fifth part of the symposium, various questions regarding hydrolysates and autolysates from fish were discussed. Rapporteur was Professor Bramstedt of Hamburg, Germany. Professor Tetuo Tomyama of Fukuoka, Japan, also took part in this discussion.

Lastly, there were three lectures of more general content. Dr. Atsushi Watanabe of Japan gave an account of the first edition of the Japanese standards of food additives, published on March 15, 1960. Dr. H. G. Luther of New York gave a report on problems connected with residues of antibiotics in feeds, and A. Valdecantos Jeminez, R. Pozo Fernandez and M. Estada Girauta—all of Madrid—reported on the use of antibiotics and thickening agents in the preparation and preservation of fowl by freezing. **[The End]**

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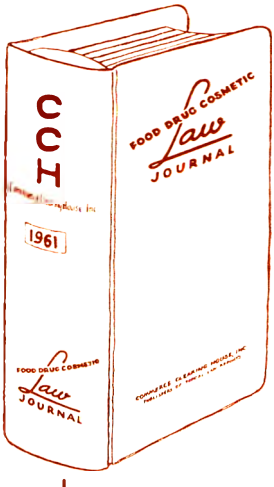

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