VOL. 17, NO. 4 APRIL 1962

Food-Drug-Cosmetic Law JOURNAL

Antibiotic Certification—A Reappraisal After 16 Years' Experience

. . . . . FRANK A. DUCKWORTH

Recent Developments in Drug Labeling Regulations and Interpretations

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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.

April, 1962
Volume 17 • Number 4

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

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VOLUME 17 NUMBER 4

Printed in the United States of America

REPORTS

TO THE READER

Antibiotic Certification.—This month's JOURNAL contains another of the papers presented before the New York Bar Association Section on Food, Drug and Cosmetic Law which was held January 24, 1962. *Frank A. Duckworth,* an assistant secretary for Charles Pfizer & Company, Inc., reappraises advancements that have taken place in antibiotic certification in the past 16 years. He concludes his discussion by saying that he hopes "that further discussions of antibiotic certification will take into account the present state of knowledge regarding the manufacture and testing of these products and that Congress will not extend certification to other products on the general and vague proposition that, 'What's good for the goose is good for the gander.' After all, these geese have come a long way since 1945." This article begins on page 229.

Drug Labeling Regulations and Interpretations.—*Vincent A. Kleinfeld* reports on recent developments in this field in an article which appears at page 238. The legislative history of the Food, Drug and Cosmetic Act is one of strife and ultimate compromise. He observes that "one of the most controversial and bitterly contested features of most of the bills which were introduced was the vesting of jurisdiction over advertising, as well as labeling in the Food and Drug Administration, rather than in the Federal Trade Commission." His interesting analysis will be of interest to many.

Chemical Residues and Additives in Food and Fibre.—"Our ingenuity and initiative enabled us to make tremendous progress in improving our food supply in terms of safety, nutritive value, abundance and variety in the years just preceding the enactment of the Food Additives Amendment. But we need to continue to advance in these fields if we are to keep our ever growing population well fed at reasonable prices." The President of the Food Law Institute, *Franklin M. Depew,* made this statement, pointing out that the new Food Additives Amendment is of prime importance in this field. Chemical residues and additives in food present a special problem, as well as a special responsibility to those involved in its regulation. The law was intended to work sensibly so that it will not prevent further improvement in the quality, variety and nutritive value of food, declares Mr. Depew, whose article appears at page 249.

Food Fads and Nutritional Quackery.—The Deputy Director of the FDA Bureau of Enforcement, *K. L. Milstead,* offers an article on a subject that is of great interest to the American consumer, who, he says, "has become health conscious, diet conscious, weight con-

scious, vitamin conscious, mineral conscious, fat conscious and protein conscious." He says that unfortunately the consumer has limited knowledge to deal with these new "consciousnesses." Various people have sought to take advantage of this lack of knowledge by undermining the public's confidence in the nutritional value of staple foods. By exposing the quacks through legal action and publicity the Food and Drug Administration hopes to put an end to "this mockery of medical and nutritional science." This timely commentary begins on page 255.

FDA and Consumer Protection.—At the fifty-fifth annual convention of the National Canners Association *George P. Larrick* spoke on the development of the inspection process during the past 23 years. He explains the extent of factory inspection. The present law, he says, "empowers our representatives to inspect all pertinent equipment, finished and unfinished materials, containers and their labeling." He concludes by praising the canning industry for their contributions in food processing and in food regulation and asking their continued cooperation. The talk is presented on page 266.

Food Additives.—*John L. Harvey*, Deputy Commissioner of the Food and Drug Administration is the author of an article which begins at page 272. He explains the problems involved in regulating the Food Additives Amendment and the steps FDA used explain to the public its meaning and its coverage. He notes that "now that industry has become knowledgeable about this law and understands how it operates, we no longer encounter a 'fear' attitude. Similarly, there was a time when some considered the term 'food additive' as a term of approbation when applied to their product. Now, however, we find that there is a recognition that the existence of an authorizing regulation gives a product a stature it did not have earlier." Both this amendment and the Color Additives Amendments are examples that industry and government are united in an effort to make foods, drugs and cosmetics marketed in this country "as safe as it is humanly possible to make them."

International Aspects of Food and Drug Legislation.—The Foreign Law Editor of the FOOD DRUG COSMETIC LAW JOURNAL, *Julius G. Zimmerman,* presents a selected bibliography of works in this field. This list, we feel will be a valuable as well as interesting aid to many of our readers. It appears at page 282.

Research Conferences.—The Gordon Research Conferences for 1962 will be held from 11 June to 31 August in the following New Hampshire sites: Colby Junior College, New London; New Hampton School, New Hampton; Kimball Union Academy, Meriden; and Tilton School, Tilton.

It is hoped that each conference will extend the frontiers of science by fostering a free and informal exchange of ideas among persons actively interested in the subjects under discussion. The purpose of the program is to bring experts up to date on the latest developments, to analyze the significance of these developments and to provoke suggestions concerning the underlying theories and profitable methods of approach for making progress. The review of known information is not desired.

In order to protect individual rights and to promote discussion, it is an established requirement of each conference that no information presented is to be used without specific authorization of the individual making the contribution, whether in formal presentation or in discussion. Scientific publications are not prepared as emanating from the conferences.

Additional information concerning the conferences can be obtained by writing W. George Parks, Director, Gordon Research Conferences, University of Rhode Island, Kingston, Rhode Island.

Vol. 17, No. 4 April, 1962

Food·Drug·Cosmetic Law
Journal

Antibiotic Certification — A Reappraisal After 16 Years' Experience

By FRANK A. DUCKWORTH

The Author Is an Assistant Secretary for Charles Pfizer & Company, Inc. He Presented This Paper Before The New York Bar Association Section on Food Drug and Cosmetic Law on January 24, 1962.

OVER THE PAST TWO YEARS the subject of antibiotic certification has been discussed in legislative hearings and by a special advisory committee appointed by the Secretary of Health, Education and Welfare. An amendment to the antibiotic certification sections of the Federal Food, Drug, and Cosmetic Act has been proposed in Senate Bill 1552 and is reported to be included in the so-called "omnibus bill" to be offered by the Administration. In view of this, it is timely to reappraise this important aspect of federal drug control.

Under Section 502(1) of the Act a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any derivative thereof, is misbranded unless it is from a batch certified or released under Section 507 of the Act. (Derivatives include dihydrostreptomycin, tetracycline and demethylchlortetracycline.)

Under Section 507, the Secretary of Health, Education and Welfare is given authority to promulgate regulations providing for certification of these products. Such regulations are directed to include such characteristics of strength, quality and purity as are considered by the Secretary as necessary to insure safety and efficacy of use. The statute directs that regulations prescribe: (1) standards of identity, strength, quality and purity, (2) tests and methods of assay, (3)

effective periods for certification and conditions under which certificates shall cease to be effective, (4) administration and procedure and (5) such fees as are necessary to provide, equip and maintain an adequate certification service.

The statute also requires that the Secretary exempt any drug or class of drugs from these requirements when, in his judgment, the requirements of the section are not necessary to insure safety and efficacy of use.

These sections were inserted in the Act to apply to penicillin in 1945. In 1947, streptomycin was made subject to certification, and two years later, Aureomycin, chloramphenicol and bacitracin were added.

Insulin is the only other drug product that is required to be certified on a batch by batch basis, with the manufacturer paying FDA a fee to perform assays regardless of whether the manufacturer has already adequately tested the drug. Coal-tar colors are also subject to certification but they, together with insulin, constitute less than 30 per cent of batches of products certified. Over 70 per cent are antibiotics. Fees for certification services run well over $1,000,000 per year. The Controller General has reported that in 1959 approximately 150 man-years of scientific, technical and administrative effort were devoted to this program.

Furthermore, within the last year FDA has proposed three amendments to certification regulations which would materially increase these already heavy costs to manufacturers and the government. In July, 1961 an increase in batch certificaton fees of 30 per cent was proposed. In the same month FDA suggested that the Administration test the nonantibiotic active ingredients in certifiable products, and on January 20, FDA proposed a number of amendments materially increasing the samples of penicillin and penicillin-containing drugs to be tested. If these amendments were adopted, companies in this field could expect to pay out millions of dollars over the next few years over and above the millions that would be expended even without such amendments in the regulations.

Antibiotics Not Subject to Sections 502(1) or 507

Antibiotic products not subject to Sections 502(1) or 507 include: Amphotericin, carbomycin, colistin, cycloserine, erythromycin, fumagillin, gramicidin, griseofulvin, kanamycin, neomycin, novobiocin,

nystatin, oleandomycin and triacetyloleandomycin, oxytetracycline, paromomycin, polymyxin, ristocetin, tyrothricin, vancomycin and viomycin. These products have been marketed under the "new drug" provisions of the Act. The manufacturers produce and assay these products under their own responsibility but subject to stringent penalties if the product fails to measure up to requirements imposed by the Act or regulations or by their effective new drug applications.

Regardless of the long history of effective and safe use of "new drug" antibiotics, proposals have been made from time to time that all antibiotics be made subject to certification. This proposal was originally presented some 16 years ago when a decision had to be made as to whether streptomycin should be handled under the new drug section or under certification.

Penicillin had been placed under certification to coincide with release of the drug for general sale to wholesalers and retailers by removal of war-time controls, and to permit the continuation of batch testing by FDA which had been carried out on behalf of military purchasing agencies under a plan prepared by the War Production Board. The industry consented to the penicillin certification amendment and advised Congress that its:

collaboration on the bill was predicated on three principles:

(1) Assurance that certification was not to be extended generally;

(2) Expectation that improved methods of production and testing would in a reasonable time warrant termination of the certification procedure; and

(3) Assurance that the Food and Drug Administration would give fast service in running and reporting its tests and assays.

Neither the Administration nor any other supporter of the bill in any way denied that this was the understanding. As a matter of fact, everything that was said by such persons was consistent with the industry's understanding that the "requirement for certification is fully expected to be a temporary matter."

Congress was advised by the Administration as follows:

It is recognized that control measures of this character are essential only in such special cases as insulin and penicillin products. Because of the newness of penicillin and the possibility of developments in manufacturing technology and otherwise that may obviate the need for special control the suggested amendment provides for the termination of certification requirements with respect to any penicillin product whenever the facts warrant.

When streptomycin came along shortly thereafter, the Food and Drug Administration proposed criteria for a general amendment to the Act to provide for certification of all drugs that are:

. . . highly efficacious for one or more serious diseases suffered by a substantial segment of the population—and—because of unusual difficulties inherent in its process of manufacture or in the method of testing finished lots it is likely to fail to meet standards of identity, strength, quality and purity appropriate to insure safety and efficacy of use.

Considerable opposition was expressed to this proposal. First, the standards were expressed in such generalities that little protection would be afforded against arbitrary interpretations. Only a short time before, spokesmen for the Administration had stated on numerous occasions that they would not seek the extension of this special type of control to drugs generally, and that they did not have in mind "the extension of the principle of pretesting to any other product or group of products."

The Food and Drug Administration dropped its proposal for a general amendment and instead suggested merely adding streptomycin to the provisions governing penicillin. Again, the Administration told Congress that as improved techniques in manufacture and better methods of testing are developed, the need for pretesting and certification may no longer exist, and reminded the legislators that products may be exempted from the certification requirement when that procedure is not necessary to insure safety and efficacy of use. The industry was obviously comforted by these words and, although it did not approve the streptomycin amendment, no opposition was entered.

Then, in 1949 two firms requested certification on newer antibiotics, and again the Food and Drug Administration proposed a general amendment setting forth standards for adding new antibiotics without special legislation in each case. But criteria could not be formulated and instead the final result was an amendment to the act adding chlortetracycline, chloramphenicol and bacitracin to the certification requirement.

With the great improvement in manufacturing and testing techniques between 1945 and 1950, proposals for a general amendment to require certification of all antibiotics disappeared. Instead, interest was focused on decertification of antibiotics.

Considerable attention over a number of years was devoted by FDA and the industry to developing policies for decertification. Some favored decertification on a product basis. Others favored exempting manufacturers who proved their experience and competence to produce satisfactory products. However, despite the great amount of

attention and study given this subject, only a very few products have been exempted from the certification requirement.

In view of this background, it is most surprising that in the last two years, proposals have been revived to expand the certification requirement to cover all antibiotics. These proposals seem to have grown out of statements made by a few physicians, not speaking for the medical profession but only for themselves, before the Senate Subcommittee on Antitrust and Monopoly. Their reasoning was simply that there did not appear to be any reason for limiting certification to those antibiotics discovered prior to 1950. Of course, no one argues that antibiotics discovered prior to 1950 are so different from those discovered after 1950 that only the former need be subject to certification. The issue is whether certification is needed for any antibiotics and, if so, which ones.

Prompted by testimony before the Senate Subcommittee, the Secretary of HEW appointed a Special Advisory Committee in 1960 to review policies, procedures and decisions of the Division of Antibiotics. This Subcommittee recommended that certification procedures be extended to cover "all antimicrobial agents used in the prophylaxis and treatment of infectious diseases." The reason given was that previously given before the Subcommittee; that is:

> The Committee sees no reason for limiting certification to those antibiotic preparations which happen to have come on the market prior to 1950, and further believes that all agents employed for equally serious conditions should be subject to equivalent measures of control.

Senate bill S. 1552 introduced in April, 1961 by the Chairman of the Senate Subcommittee includes an amendment to Section 502(l) of the Act so as to bring under certification all antibiotic drugs. The Department of Health, Education, and Welfare has indicated its support for such an amendment.

Report of Controller General

On the other hand, the Controller General, in a report to the Congress in September, 1961, proposed that a review be made of the need for continuation of the certification program for antibiotics. The report points out that, "While the certification program provides extensive safeguards for protecting the consumer, it requires a relatively large number of scientists and technicians for the testing work," and questioned whether this effort could not be put to better advantage.

The report made the following pertinent comments:

> The low incidence of rejection in testing products under the certification program suggests that generally a high degree of product quality has been attained by manufacturers of certified antibiotics. During fiscal year 1960, 22 batches of antibiotic drugs were rejected by FDA out of 16,601 batches tested. During the last 5 years only 2.3 batches were rejected for every 1,000 batches tested. For insulin, 350 batches were tested in fiscal year 1960, of which 1 batch was rejected.
>
> Section 507(c) of the Food, Drug, and Cosmetic Act (21 U. S. C. 357(c)) provides discretionary authority for the Secretary to modify the certification testing program for antibiotics when in his judgment less than 100 per cent predistribution testing, but not complete elimination, would be desirable with respect to a specific product or a manufacturer. It would seem that the use of such discretionary authority might be justified in some cases by the proficiency of industry in manufacturing specific products. We recognize, however, that any relaxation of 100 per cent predistribution testing would have to be based on scientific and technical judgments of HEW officials and any relaxation of the testing controls would probably have to be coupled with an intensified program of factory inspections and reviews of the manufacturers' quality controls.

The *New England Journal of Medicine* has come up with a recommendation to extend the certification requirement to all new drugs that are products of biologic processes and in which the activity, purity and potency of the product has been found to vary significantly from batch to batch. The journal suggests that the determination be made by the Division of Biologic Standards instead of FDA, and that a provision be included in the statute for removal from certification of "any drug that experience has shown can be manufactured and produced with uniform activity, potency, and purity."

It is interesting to note that both the Special Advisory Committee and the *New England Journal* do not recognize antibiotics as a special class for certification. The advisory committee speaks of all "antimicrobial" agents and the *New England Journal* speaks of all drugs produced by biologic processes.

The Citizen's Advisory Committee appointed by the Secretary of Health, Education and Welfare made the following recommendation in its report in 1955:

> . . . that the appropriate authorities should consider taking such steps as are administratively permissible under the present act to decertify antibiotics which have reached standards of identity, strength, quality, and purity which are sufficiently satisfactory to warrant decertification.

Therefore, the proposal made in S. 1552 and backed by the Administration proceeds on a different theory than that advocated by any of these groups.

In reviewing the question of whether certification is any longer appropriate for antibiotic products, we should start with the reasons that were advanced for placing penicillin, streptomycin, chlortetracycline, chloramphenicol and bacitracin under this special type of control program.

Some of the reasons advanced would apply to many types of drug products. For instance:

(1) It was stated that the products are efficacious in a number of diseases, some of which can be fatal.

But this is true of a host of drug products such as the sulfonamides, hormones, anticoagulants, antiseptics, antispasmodics, digitalis and other products for use in cardiac conditions, and many others.

(2) That the methods available for checking interstate shipments are not sufficient to assure the safety of these products.

But if this is a problem, it is one applicable to all products subject to the Act.

In arguing for this special control over penicillin and streptomycin, the principal assertion was that the drugs are produced by a biological process which is subject to vagaries inherent in all such processes.

But biological production processes are by no means unique to antibiotics. They are among the oldest and most widely used production processes known to man.

Such a process was used in the production of beer by the ancient Egyptians. Pharaoh's beer was probably cloudy and varied from jar to jar, but the vagaries in the production of this important product have not subjected it to a certification requirement during any of its 4,500 years of recorded history.

Neither is certification applicable to wine, yeast, cheese, yoghurt, buttermilk or alcohol, all of which are produced by biological processes. Nor is certification applicable to riboflavin, vitamin B_{12}, or ascorbic acid, which are produced in whole or in part by biologic processes, as are citric acid, hydrocortisone, and gluconic acid. And consider, too, the hundreds of derivatives of these substances.

"Omnibus Bill"

Furthermore, the "omnibus bill" proposed by HEW, as reported in the January 8, 1962 issue of *F-D-C Reports* ("The Pink Sheet"), would extend antibiotic certification requirements to cover products

regardless of whether they are produced by a biological process, for the term "antibiotic" would be defined as "a chemical substance produced by living micro-organisms, *or the equivalent of such a substance produced synthetically* and capable of destroying or inhibiting the growth of another micro-organism in high dilution."

Another reason advanced for certification was that testing techniques were imprecise. However, this difficulty has long since been removed. As a matter of fact, in 1955, Doctors Grove and Randall of FDA's Division of Antibiotics put together in book form a manual of assay methods of antibiotics which they described as follows:

> The present book gives practical tests and methods of assay for all of the antibiotics that are being distributed commercially in the United States today and for the various preparations and substances in which they may occur. Because of the tremendous amount of research being conducted to find new antibiotics, this book will probably not be published very long before some new ones will be introduced for clinical or other use, further adding to the list of these important drugs. It is believed, however, that such a wide variety of methods are presented that it will be a relatively simple matter to adapt them to any new antibiotics that may come along.

In 1950, Mr. Charles Crawford, then Deputy Commissioner of the Food and Drug Administration, discussed administrative decertification of antibiotics. He commented that the basic considerations responsible for the enactment of Section 507 were: first, that the drug was highly efficacious in the treatment of crippling diseases occurring among a large number of our population; second, that it was produced by biological methods with a lack of uniformity among batches of finished production; and third, that the methods of assaying the finished drug gave uncertain and variable results. Mr. Crawford seemed to admit that these original reasons might no longer apply but said:

> We do not believe that the statements describing the factual situation with respect to penicillin at the time of enactment necessarily constitute all of the factors the Administrator should consider at a future time in action under Section 507(c). (Subsection (c) deals with decertification.)

Mr. Crawford argued that the Act does not permit exempting manufacturers who have proved their competence from certification but requires decertification only on a product by product basis. But Mr. Crawford made it clear that he was talking about the duty imposed upon the Secretary by Section 507. He said:

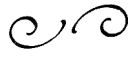
> The statement of what we think Section 507(c) means should not be taken as what we think the Section ought to be. We think the Section should be changed because we do not believe that once a firm operates under certification it should necessarily do so for all time.

Under the amendments to the Federal Food, Drug, and Cosmetic Act that have already, or will soon be, presented to Congress, the Food and Drug Administration would have even more abundant authority than it now has to control the manufacture and distribution of drug products. The Pharmaceutical Manufacturers Association has proposed that all drug manufacturers be required to register with FDA. Under the "omnibus bill" proposed by HEW, as reported in "The Pink Sheet," the Secretary would be given authority to prescribe by regulations the methods, facilities, personnel and controls to be used in drug manufacturing, processing, packaging or holding to insure that the drug's identity and strength do not differ from, and that its purity and quality do not fall below those which the drug purports or is represented to possess. Failure to meet the requirements prescribed by such regulations would render the drug adulterated.

Moreover, factory inspection authority would be considerably broadened. New drug applications could be revoked for the failure to keep required records, for failure to permit access to such records, and for failure to maintain methods, facilities and controls prescribed in the application. With all of this, it is extremely difficult to understand why the burdens and waste of batch certification should be continued, much less expanded, even if some problem that originally prompted enactment of the certification requirement still remained. And it is respectfully submitted than no such problem does remain.

Conclusion

It is hoped that further discussions of antibiotic certification will take into account the present state of knowledge regarding the manufacture and testing of these products and that Congress will not extend certification to other products on the general and vague proposition that, "What's good for the goose is good for the gander." After all, these geese have come a long way since 1945. **[The End]**



Recent Developments in Drug Labeling Regulations and Interpretations

By VINCENT A. KLEINFELD

The Author, a Member of the Washington, D. C. Law Firm of Bernstein, Kleinfeld & Alper, Presented This Paper Before the Quality Control Group of the Contact Section, Pharmaceutical Manufacturer's Association, on March 19, 1962.

THE LEGISLATIVE HISTORY of the Federal Food, Drug and Cosmetic Act reveals that during the five years of interagency and legislative strife which finally culminated in the passage of the statute, a number of compromises were necessarily arrived at in order that some law could be enacted. One of the most controversial and bitterly contested features of most of the bills which were introduced was the vesting of jurisdiction over advertising, as well as labeling, in the Food and Drug Administration, rather than in the Federal Trade Commission.

The conflict appeared to be settled by the passage of the Wheeler-Lea Act (52 Stat. 111), which provided in part that the dissemination of false advertising with respect to food, drugs, devices and cosmetics constituted an unfair or deceptive act in commerce under the Federal Trade Commission Act. The passage of the Wheeler-Lea Act, and the ultimate enactment of the Federal Food, Drug and Cosmetic Act, seemed to the unskilled eye (to those who were not familiar with, or did not yet comprehend what the executive and judicial branches could do with statutory language), to resolve the problem of jurisdiction with some certainty. To the unsophisticated, it appeared that Congress had vested in the Federal Trade Commission the function of controlling advertising, and had vested in the Food and Drug Administration the function of regulating labeling. The years which have elapsed since the passage of these statutes, however, have revealed an interesting approach whereby the Food and Drug Administration has managed to augment the scope of the Federal Food, Drug and

Cosmetic Act by exercising jurisdiction over items which would traditionally have been designated as advertising. This was skillfully done with respect to over-the-counter drugs and now, in the Kefauver era, has been carried over into the prescription area.

Labeling Interpretation

There are, in reality, two facets to the exercising of control under the Federal Food, Drug and Cosmetic Act over what would ordinarily be denominated advertising. The first arises out of the construction which the courts have placed upon the term "labeling," as used in Section 201(m). In the *Kordel*[1] and *Urbeteit*[2] decisions, the Supreme Court sustained the manner in which the word had been interpreted by the Food and Drug Administration. In the *Kordel* case, for example, the false and misleading statements of which the government complained had been contained in circulars or pamphlets distributed apart from the drugs. Some of the literature had been displayed in stores in which the products were on sale; some had been given away with the sale of the products; some had been sold independently; and some had been mailed to customers by the sellers. Notwithstanding that the literature had been shipped separately from the drugs with which it was associated, and regardless of the fact that the lapse of time between the shipments of the drug and literature was in at least one instance approximately a year and a half, the Supreme Court held that the literature, a typical advertising medium, constituted labeling which had accompanied the drugs in interstate commerce.

The Court was obviously impelled in sustaining Kordel's conviction, as it has been motivated in other food and drug cases, by the remedial purposes of the Act. Even though the case involved a criminal prosecution, and that the detailed legislative history of the Act was remarkably silent with regard to the scope of Section 201(m), the majority of the Court encountered little difficulty in construing the section as urged by the government. The basic rationale for the Court's holding was stated quite clearly in its opinion: the belief that a contrary result would create "an obviously wide loophole." It can of course be contended with some reason that loopholes, bad as they may be, should be closed by the legislative branch rather than by the executive or judicial branches.

With respect to the contention that the Federal Trade Commission had been given specific jurisdiction over advertising, the Court

[1] *Kordel v. United States*, 335 U. S. 345 (1948).
[2] *United States v. Urbeteit*, 335 U. S. 355 (1948).

adverted to the fact that, in the evolution of the Federal Food, Drug and Cosmetic Act, the ban on false advertising had been eliminated and its control transferred to the Federal Trade Commission. The Court declared, nevertheless, that it had searched the legislative history in vain to find any indication that Congress had intended to eliminate from the Act advertising which performs the function of labeling.

There is now no doubt, therefore, that where drugs and advertising material have a common origin and a common destination, and where the literature is designed for use in the sale of the drugs, explains their use and is an essential supplement to the label attached to the package, the products and the literature are interdependent and accompany each other in interstate commerce. It is now settled law that this type of advertising matter is encompassed by the Federal Food, Drug and Cosmetic Act.

Subsection on Misbranding

The second facet of the exercising by the Food and Drug Administration of jurisdiction, indirect though it may be, over advertising is the manner in which the agency and the courts have interpreted Section 502(f)(1) of the Act. The subsection is remarkably terse. It declares merely that a drug or device shall be deemed to be misbranded unless its labeling bears adequate directions for use, although a proviso is added to the effect that where any requirement as to such directions, as applied to a drug or device, is not necessary for the protection of the public health, the secretary shall promulgate regulations exempting the drug or device from the requirement. The legislative history of the Act contains no direct guidance as to the congressional design with regard to the scope of the section in connection with claims made or diseases referred to in the advertising of drug products.

In December of 1938, the Food and Drug Administration issued a regulation quite similar to the regulation now in existence. This provided that directions for use under Section 502(f)(1) might be inadequate by reason of the omission of directions for use in all conditions for which the drug or device was prescribed, recommended or suggested in its labeling, "or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used."

The Food and Drug Administration has maintained, and this approach has been sustained by the courts, that the design of Section 502 of the Act, as a whole, is "to make self-medication safer and more effective, and to require that drugs moving in interstate commerce be properly labeled so that their use as prescribed may not be dangerous to the health of the user." The courts have accepted the proposition that it cannot be determined whether directions for use are adequate, as required by the Act, unless the purposes for which the drug is to be consumed are set forth. Likewise, if the labeling merely states dosages, without revealing the conditions and ailments to which they refer, it is impossible to ascertain whether the product complies with Section 502(j), which provides that a drug is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

Statement of Drug's Purpose

Once these assumptions were accepted, the ruling of the courts followed that the labeling of a drug which a consumer purchases over-the-counter must state the ailments for which the product is to be used and directions for its use in such ailments, no matter in what media the drug is held out for such use. If the manufacturer or distributor of a drug product, in newspaper or magazine advertising, for example, recommends his product for use in the treatment or cure of various diseases, the courts have held that the labeling must contain directions which are aimed at the use of the drug in the treatment or cure of such diseases, including their names. Since listing the names of conditions for which the product was not efficacious would result in a Section 502(a), "false or misleading" charge, the distributor is faced with a Scylla-Charybdis dilemma; he must choose between regulatory proceedings based on either Section 502(f)(1) or Section 502(a).

The rationale utilized by the courts which have considered the problem was set forth with clarity in a leading case[3] as follows:

> The words "adequate directions for use," necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purposes are drugs used? Obviously, as a remedy for some ailment of the body. It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any

[3] *United States v. Instant Alberty Food*, 83 F. Supp. 882 (D. C., D. C., 1949).

means, held out to the public as an efficacious remedy be listed in the labeling, together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment.

The district court was clearly motivated in this case, as the Supreme Court was in the *Kordel* case in connection with the "accompaniment" problem, by the fact that a contrary construction of Section 502(f)(1) would provide the manufacturer or distributor with a convenient method by which he could evade the purposes of the Act. The court declared:

> Any other construction of Section 352(f)(1) [502(f)(1) of the Act] would provide the manufacturer and shipper with a convenient loophole through which he could evade the Act with resulting danger to public health. He need only include in the labeling either dosage directions alone, or with the addition of one or more bodily diseases or ailments for which he claims the drug is efficacious, and by a contemporaneous advertising campaign lead the public to believe that the drug is a remedy for a multitude of ailments. In such cases . . . there is no section of the Act which protects the public against the resulting harm.

Again, a "loophole" was being closed by the courts.

In the Kefauver era in which the drug industry is now living, the Food and Drug Administration determined to increase its regulatory control of the labeling (which now includes, of course, material which would ordinarily be considered advertising) of prescription drugs. The amendments to the regulations under Section 502(f)(1) of the Act (the directions for use section), promulgated by the Food and Drug Administration last year, make material changes with respect to the labeling of prescription drugs, both for human and veterinary use. These amendments are extremely far-reaching.

While the regulations relating to prescription drugs are nominally based on the authority given the Food and Drug Administration to exempt the labeling of certain drugs from bearing adequate directions for use, in effect they state the criteria that will constitute adequate directions for use for all prescription drugs.

Limitations to Dispensing Prescriptions

The Federal Food, Drug and Cosmetic Act limits to prescription dispensing all drugs for human use which contain certain habit-forming narcotic or hypnotic substances, and all drugs for human use which, because of their toxicity or other potentiality for harmful effect, or because of their method of use or collateral measures necessary to their use, are not safe for use except under the supervision of a licensed physician. Through the new regulations, the Food and

Drug Administration has tightened its control not only over the labeling of these prescription drugs but also, especially where "new drugs" are concerned, over advertising as well.

Specifically with respect to prescription drugs for human use, the regulations provide that these drugs shall be exempt from the requirement of bearing adequate directions for use as long as the following conditions are met:

1. The drug, prior to its actual dispensing on prescription, is in the possession of one lawfully entitled to possess the drug.

2. The label of the drug bears the statement "Caution: Federal law prohibits dispensing without prescription"; informs as to the recommended or usual dosage of the drug; specifies the route of administration of the drug if it is not for oral use; states the quantity or proportion of each active ingredient under its common or usual name; if it contains certain narcotics, the quantity or proportion and the name of the narcotic with the legend "Warning—May be habit forming" and the quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or their derivatives as specified by regulation. In addition, the label must contain the names of all inactive ingredients if the drug is for other than oral use, and, if it is a parenteral, the quantity or proportion of each inactive ingredient. However, flavors, perfumes and colors may be designated as such. Finally, the label must contain an identifying number through which the complete manufacturing history of the particular lot of drug can be determined. The outside container of a drug must bear the same information contained on the label.

3. If the immediate container of the drug is too small or otherwise unable to bear a label containing all of the information specified, and is packaged in an outer container from which it is removed for dispensing or use, it is permissible to place the prescription legend on the outside container of the drug only. In that event, the dosage instructions, route of administration and list of inactive ingredients (if required) can be contained in a package insert or other labeling on or within the package from which it is to be dispensed. The quantity or proportion of each active ingredient, and a listing of narcotics and other ingredients already specifically named, however, together with

the lot number, must appear on the label of the immediate container itself. If the immediate container is a dispensing tube, the identifying lot or control number may be on the crimp of the tube.

4. A recent amendment to the regulations refers to the situation where the dosage for a prescription drug varies within extremely wide limits, so that it may not be possible in all cases to present an informative or useful statement of the recommended or usual dosage in the space available on the label or carton. The Food and Drug Administration has declared, in a Statement of General Policy or Interpretation, that in such a situation compliance with the requirement would be met by a statement such as "See package insert for dosage information" and the detailed information is contained in the insert.

Provisions

The regulations provide that all of a prescription drug's labeling, including direct mailings to physicians and pharmacists and material left by detail men, which contains information relating to the use or dosage of the drug, must also convey information concerning the effects, dosages, routes, methods and frequency and duration of administration and any relevant hazards, contraindications, side-effects and precautions, and must state all of the conditions for which the drug is represented to be of use, as well as the composition of the drug.

The effect of the amendments pertaining to the new drug regulations is to require that the labeling of all prescription new drugs bear the same information as is required for prescription drugs in general. In addition, however, the Food and Drug Administration has augmented its control under the New Drug Section, to a limited degree at least, with regard to the advertising of new drugs, prescription as well as over-the-counter. In this respect, the regulations require that the new drug application state that the advertising of all new drugs will limit the recommended usage for the drug to the same conditions as stated in the drug's labeling. It may be debated whether this adds to the authority formerly claimed by the Food and Drug Administration. It does provide, however, a somewhat easier means for enforcing the authority if the agency possesses it.

In addition, the amendments to the new drug regulations provide that the application shall be conditioned upon the fact that no changes will be made in the components, composition, manufacturing methods, facilities, controls and labeling of the drug until a supplemental ap-

plication has been filed and becomes effective, or until the Food and Drug Administration gives written notification that no supplemental application is required for the contemplated changes.

The amendments to the new drug regulations also provide for an inspection of the facilities used to produce a new drug when the written description of the facilities contained in the new drug application is not sufficient to warrant the conclusion that the drug is safe. Pending such an inspection, the application may be made conditionally effective, but marketing of the drug may not take place until the inspection has been conducted and the applicant informed in writing that the new drug application has been made fully effective. In line with this inspection authority, the Food and Drug Administration seems also to be claiming the right to examine records relating to the drug.

What I have said covers the more significant changes in the regulations. I have not offered any opinion on the validity or enforceability of these amendments to the regulations. As a matter of academic interest, it is interesting to speculate on the results in the event a drug manufacturer were to take the position that he did not wish to be favored by being granted an "exemption" by regulations issued under Section 502(f)(1) of the Act, and merely wanted to set forth adequate directions for use in his labeling in compliance with the statutory language. Of course, the government takes the position that there can be no adequate directions for use of a prescription drug. Whether this is true in every factual situation is a matter for conjecture. Is it not reasonable to hold that the prescription legend constitute adequate directions for use for a prescription drug? Does a Constitutional problem arise if it is a fact, as contended by the government, that there is no way in which statutory language can be complied with except by taking refuge behind an exemption from the statute? And can the granting of an exemption (which the recipient must accept) from the requirement of "adequate directions for use" compel the setting forth of hazards, contraindications, side-effects, and precautions?

It is also interesting to speculate as to the effect of an assertion by a drug manufacturer that the Act does not require that every piece of printed material constituting labeling must bear adequate directions for use and warnings. Is it definitely established as a matter of law that promotional material forwarded to physicians is "labeling" under Section 201(m) of the Act? What are the legal consequences if a particular piece of printed material forwarded to physicians does not

comply with the regulations? Can the requirement of package inserts be enforced if all physicians and pharmacies have already been furnished with the full disclosure of information by means of a reference card or some similar medium? Whether the statutory authority relied upon by the government for the issuance of the regulations is sufficient to support them might not be entirely free from doubt if the area concerned were not the food and drug field.

Decision Left to Manufacturer

The regulations provide that the information required by the regulations may be omitted from the dispensing package of prescription drugs if the directions, hazards, warnings and information for use of the drug "are commonly known to practitioners licensed by law to administer the drug." It is clear that the regulations theoretically left in the manufacturer the decision with respect to whether directions, warnings, and so forth, are "commonly known" to doctors. The regulations merely provide that, upon written request stating reasonable grounds therefor, "the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package." Apparently the government may be regretting this slight obeisance to the discretion and judgment of industry. For in announcing last month, that new drugs and drugs requiring certification will also be considered for "exemption" [note the use of that term] from the full disclosure package information regulations, the interesting statement was made that:

> The change in regulations now permits drugs for human and veterinary use in all categories to be exempted by the Commissioner when statements containing convincing grounds for exemptions have been submitted in writing.

It seems reasonably clear that exemptions of particular drugs from the full disclosure requirement will be dependent upon how well known the drug is to the general medical profession. It is doubtful that the fact that a particular drug is used by a specialized segment of the medical profession, and has attributes which are well known to that group, will qualify the drug for exemption. It appears, also, that exemptions will not be governed by the length of time a drug has been on the market, by the fact that a new drug has lost its new drug status, or by the fact that a drug may appear in one of the various compendia. Actually, it is probable that relatively few exemptions from the full disclosure requirement will be granted by the Food and Drug Administration. On December 28 of last year, the Food and Drug Administration exempted only ten drugs.

It is to be borne in mind that a manufacturer remains free, as a matter of law, to decide for himself whether his drugs are subject to the regulations. Of course, the danger inherent in such a course of conduct is that the Food and Drug Administration may disagree and the manufacturer may find himself in court, usually a fate worse than death—in this field at least. In my view, however, if a drug manufacturer obtains the opinion of recognized experts in various parts of the country, and these experts conclude that the information otherwise required by the regulations is commonly known to physicians, this conclusion should be accepted by the courts.

Distributing Medical Journal Reprints

An interesting question relates to the distribution of reprints of articles appearing in medical journals. If the article is distributed by the author or publisher, who is in no way associated with the drug firm, there is no requirement that full disclosure accompany the reprint. But if the article is distributed on behalf of the drug manufacturer, full disclosure would be required. Further, in the case of a new drug, if the article indicates that the drug may be used for conditions not covered by the new drug application, or, in the case of an old drug, for purposes other than those generally recognized, the manufacturer should distribute the article only in response to a specific request from a physician. It should not be distributed en masse. Even with the limited distribution pursuant to physicians' requests, it would be advisable to notify the physician that the article relates to uses for the drug which are not established, and a "full disclosure" insert should be enclosed.

The question of the status of house organs and of material sent to detail men is also of particular interest. It seems clear that the Food and Drug Administration will take the position that material of this character constitutes "labeling," and consequently should contain full disclosure whenever mention is made of the uses for any prescription drug which is not exempt. In my opinion, difficult enforcement problems will be encountered by the Food and Drug Administration if it decides to police this area. Nevertheless, it is a further indication of how far the agency contemplates going.

Full Disclosure Regulations

It appears to be the position of the government that if any indications for use of a product are given in a price book or catalogue, full

disclosure must be provided. The Food and Drug Administration apparently holds the view, also, that if drugs in a catalogue are listed under a general heading such as "hypertensive agents," full disclosure is required. Only if a reference to a drug falls into the category of a reminder piece, would full disclosure not be required in the opinion of the government. Presumably the courts will eventually decide whether to accept this administrative construction of the Act.

As indicated, the argument which attempts to sustain the "full disclosure" regulations proceeds upon the basis of an interesting assumption. This is that the only manner in which prescription drugs can be labeled so as not to violate the "adequate directions for use" provision of the Federal Food, Drug, and Cosmetic Act is by adhering to regulations exempting the drugs from complying with the provision. The legal basis of this gambit is not clear, and has not been definitely ruled upon.

I must conclude by adverting to the decision I came to in the halcyon years of the past with respect to the interpretation and enforcement of the Federal Food, Drug, and Cosmetic Act. In other statutory areas, the problem for the legal specialist is to examine the problem, scrutinize the letter of the law and its legislative history, find and carefully analyze the cases, weigh the policy considerations, if any, and then advise the client whether the course of conduct he wishes to take complies with the requirements of the law. A lawyer, in such a situation, is ordinarily willing to give a firm opinion to his client. This procedure is presumably followed by the specialist in the food and drug area. He, however, must then turn to the second phase of his problem, since it arises in his field. He may have come to the conclusion, based on a careful and thorough study of the question, that the course of conduct the client wishes to pursue meets the requirements of the Federal Food, Drug and Cosmetic Act. He must now try to ascertain, however, whether the position of the government may be contrary; and if so will the courts, by some fortunate and most unusual circumstance, pay the slightest attention to his opinion and disagree with the government's position. Or will the maxim so often heard in these cases be employed, to the effect that "legal technicalities" (by definition these being any point of view contrary to the government's) must not be permitted to interfere with the "remedial purposes of the Act." Presumably for this reason, it will be a most unusual and daring company which will invite a court challenge of portions of the regulations. **[The End]**

Regulatory and Developmental Problems Attendant Chemical Residues and Additives In Food and Fibre

By FRANKLIN M. DEPEW

The Food Law Institute President, Franklin M. Depew, Served as Chairman of the Third Session of the American Chemical Society Symposium on the Role of Chemicals in Modern Food and Fibre Production. He Presented This Introductory Statement at the Session on March 21, 1962.

PRESIDENT KENNEDY in his 1961 Proclamation urging us to observe Law Day asserts that to remain free the people must "cherish their freedoms, understand the responsibilities they entail, and nurture the will to preserve them." I suggest that it is appropriate that this statement be made the keynote of our discussions relative to regulatory and development problems attendant to the use of additives in food and fibre. Unless government and industry work together to preserve these freedoms, our emotions, rather than our intellects, may govern our future activities in this field.

Our ingenuity and initiative enabled us to make tremendous progress in improving our food supply in terms of safety, nutritive value, abundance and variety in the years just preceding the enactment of the Food Additives Amendment. But we need to continue to advance in these fields if we are to keep our ever growing population well fed at reasonable prices.

Food Additives Amendment

The recently enacted Food Additives Amendment is the law of prime importance in this field. It amends the Federal Food, Drug

and Cosmetic Act to require the prior approval by the Secretary of Health, Education and Welfare of all "food additives." A food additive is basically defined to be a substance intentionally or incidentally added to food, except one already approved under the provisions of existing law or one which is generally recognized among experts competent to evaluate its safety as having been adequately shown to be safe under the conditions of its intended use.

The refusal to approve a feed additive is subject to an optional administrative and judicial review, which is required by the Administrative Procedures Act and which follows the traditional pattern of review under the Federal Food, Drug and Cosmetic Act, with one important exception. The order made after the administrative hearing must be based upon a fair evaluation of the entire hearing record and the court may not sustain the order unless it complies with that fair evaluation requirement. Thus the law prescribes a new statutory criterion requiring that a high standard of fairness be observed in rule-making under this Amendment. This language was secured because manufacturers expressed their concern that without it the wide administrative control over the use of food additives provided by the Amendment would not be subject to adequate checks.

Food is such a basic need we all tend to become unduly alarmed at the mere thought that any food is not absolutely pure or absolutely safe. But is there any such thing as absolute safety in any aspect of our daily lives? We do not react as emotionally to other risks as we do to the possibility that an ingredient in our food may be unsafe in certain amounts. An example of this emotionalism has been reported by John L. Harvey, Deputy Commissioner of the Food and Drug Administration. When the FDA recommended to Congress that the effective date of the Food Additives Amendment could be postponed consistent with protection of the public health, when action had been taken in the past by the filing of an application for extension, or petition to establish safety, the FDA was inundated with letters abusing the FDA for an alleged utter disregard of the consumer's interest. These letters completely overlooked the fact that no extensions could be granted under the proposed legislation without finding that the extensions involved no undue risk to the public health.

Another example of emotionalism with regard to food is the fact that the Congress thought it necessary that a clause be added to both the Food Additives Amendment and the Color Additive Amendments which forbids the issuance of any regulation permitting the use of any amount of any substance which "is found to induce

cancer in man or animals." Here, even the FDA has indulged in an emotional response to the problem of cancer, for it has in recent years strongly supported the clause, though the clause may work to prevent the establishment of even safe levels, when definable, of many useful chemicals some of which may be highly beneficial at these safe levels. The President's Science Advisory Committee in its report on Food Additives studied this clause and recommended that each proposed additive be considered carefully on its own merits. In "Food and Science . . . Today and Tomorrow" by William J. Darby, M. D. and Gwen Lam, Public Affairs Pamphlet No. 320, it is stated that "there is evidence that some substances are essential to life at one dosage and known carcinogens at another higher dosage." Since Doctor Darby is Chairman of the Food Protection Committee of the Food and Nutrition Board, National Research Council and a member of the Council on Foods and Nutrition of the American Medical Association his views are entitled to substantial weight.

Responsibilities Involved

These examples illustrate to all of us who are actively engaged in this field, be we scientists or lawyers, industrialists or regulators, that we have a special responsibility to endeavor to conduct ourselves in relation to the Food Additives Amendment so that we will not permit our judgment to be influenced by arguments based on emotional appeals. We need to approach the problems of this food additive law with a determination that we will make the law work sensibly, as it was intended, so that it will not prevent the further improvement of quality, variety and nutritive value of our food. This is the approach which has been faithfully followed by the Food Protection Committee. If we tap the reserve springs of ingenuity which have welled abundantly from our people in industry and government in the past we can expect to be successful in this endeavor.

One such approach would be for industry representatives to establish more expert panels to support the general recognition of safety of additional substances, such as was done by the Flavoring Extract Manufacturers' Association. As I have pointed out on previous occasions, industry lawyers who supported the enactment of the Food Additives Amendment expected that the exception in this law relative to substances generally recognized as safe would be used by industry and the FDA to a much greater extent than it has to avoid unnecessary regulatory control of many substances. This exception for substances generally recognized as safe expresses our govern-

ment's philosophy of regulation rather than permission control. The language chosen by the legislators contemplates that a food manufacturer or a group of manufacturers may conclude that a substance is generally recognized as safe for its intended use by experts competent to evaluate its safety.

Incidental Additives Problem

The problem of safety clearance of incidental additives resulting from chemical residues in packaging materials (fibre or otherwise) has taken up the bulk of FDA's time and effort in the food additive field. Petitions for food additive regulations for such additives involved approximately 1,675 chemicals as of March, 1961, according to a statement by J. Kenneth Kirk, Assistant Commissioner, before the American Society of Bakery Engineers. It has also required large expenditures and intensive studies by industry which have not produced any evidence that any old or new packaging material would have been a serious hazard to health if the Food Additives Amendment had not been enacted. It has even been suggested that a vigorous effort be made to secure FDA's support for Congressional reconsideration of the Act insofar as it relates to incidental additives. These problems might possibly have been solved by expert panel determinations that the various substances were generally recognized as safe.

Contrary to the expectation of the industry lawyers who supported the enactment of the Food Additives Amendment, we thus find the law is now operating almost completely as a permission control or license law. Under a license law conduct is controlled by the government by permitting activities to be carried on in a certain prescribed manner. License laws are authoritarian in their approach to legal problems. They are contrary to our basic philosophy of regulation whereby a law objectively defines the conduct prohibited as wrongful and violators are prosecuted. Such regulatory laws permit freedom of action on the part of the regulated to determine what actions are permitted, with the final responsibility being placed in our courts to determine what is prohibited. The impatience with this method of regulation that has been expressed in some quarters reveals a failure to recognize the great benefits we have received from the safeguards provided by the courts.

The law is operating as a permission control law largely because purchasers of ingredients have insisted on FDA approvals or clearances for safety. They became uninterested in having a supplier tell

them that a given substance was generally recognized as safe unless the FDA included that substance on one of its published GRAS lists. The net result in the commercial world has been to foreclose individual determination of GRAS status and to give FDA nearly as much control over exempt substances as it has over those which Congress placed under FDA jurisdiction. This timidity is undoubtedly due to a fear of an emotional reaction by the consumer if the conclusion by an expert panel that a substance is generally recognized as safe should be questioned by FDA.

FDA Commended

Few government agencies have as consistently over the years demonstrated so fairminded an objectivity in the performance of statutory duties as has the FDA. FDA enforcement and regulation have been conducted in such a way as to satisfy the general body of citizens that it is proceeding with a reasonable regard for the balance between the public interest which it protects and the private interest which it disturbs. In the main the attitude and conduct of the FDA and the form of its procedures have been such that the regulated industries feel they are being dealt with fairly.

An exception to this was the manner of handling the "cranberry incident" pursuant to Section 705 of the Act. This section permits the Secretary to give information on the facts to the public in any case which he believes there is danger to the public health. The Secretary advised the public that cranberries were contaminated with residues of aminotriazole. I find there is a strong industry sentiment that this was not a fair way of handling the situation under the existing facts including the possible danger to the public health. How much this action may have contributed to industry's failure to make safety decisions on its own responsibility is difficult to evaluate.

This brief history discloses that at present the authoritarian approach to the problems of food additives has been widely adopted. It is regrettable that this is partly due to the failure of responsible businessmen to realize their responsibilities and to rise to them. Industry members need to rededicate themselves to the ideals of our heritage of law. They must have a living faith in freedom's fundamental concepts and a constant resolution to preserve them. They must plan and work to reconcile democratic safeguards and standards of fair play in the field of administrative action with the effective

conduct of government. They must so act as to constantly remind the FDA of its responsibilities in maintaining these ideals.

FDA personnel need to approach their tasks under the Food Additives Amendment in accordance with these concepts. To a considerable degree, the successful operation of any procedure requires cooperative effort by all the parties. There exists a tremendous need for mutual understanding in order that the many problems in this field may be fairly solved without impairing American enterprise or endangering the health of the consumer. **[The End]**

FALSE REDUCING AND HEALTH CLAIMS

The Food and Drug Administration today announced two seizures of safflower oil products with copies of the diet book, *Calories Don't Count,* on charges of false reducing and health claims.

FDA said the seizures were the third and fourth to include the book as the source of false and misleading claims for safflower oil. Copies of *Calories Don't Count,* by Herman Taller, M. D., obstetrician and gynecologist, were seized last January in two actions in New York City charging they were being used to represent falsely that safflower oil capsules are effective for weight control without regard to total caloric intake.

FDA said United States marshals have seized quantities of safflower seed oil, safflower mayonnaise and safflower oil capsules with Vitamin B-6 at Thalhimers Department Store in Richmond. Copies of the book, *Calories Don't Count,* used in promoting sales of the safflower oil products, were also seized as well as two display placards prepared by the dealer reading in part, "For the newest fashion in dieting . . . Safflower Oil and Gluten Breads" and "Recommended For Slimming Diets—Safflower Oil, Safflower Capsules, Gluten Flour, Gluten Toast."

United States marshals have also seized quantities of safflower oil and safflower oil capsules with Vitamin B-6 at the Forks Township Pharmacy, Easton, Pennsylvania. Included were copies of *Calories Don't Count* and a placard reading in part, "How To Lose Weight Without Even Trying—Dr. Herman Taller's Sensational New Book *Calories Don't Count.*" FDA said the placard was prepared by the pharmacy for displaying and promoting sales of the seized products and books.

Seizure papers, filed in the federal district courts at Richmond and Philadelphia charge the safflower oil products were misbranded under the Federal Food, Drug, and Cosmetic Act because of false representations in the books, placards and other sales material that they are effective for the following: To control body weight, to reduce and maintain slimness even though consuming many thousands of calories daily without regard to total caloric intake; to lower and control the cholesterol level of the blood; for the treatment and prevention of arteriosclerosis, heart disease, diabetes and heartburn; to improve the complexion, increase resistance to colds and sinus trouble; to promote health, increase sexual drive and for other purposes.

Foods Fads and Nutritional Quackery as Related to Dairy Products

By K. L. MILSTEAD

This Paper Was Presented at the Annual Meeting of the American Butter Institute and the National Cheese Institute on April 10, 1962, in Chicago. Mr. Milstead Is Deputy Director, Bureau of Enforcement, Food and Drug Administration.

IT MAY SEEM somewhat paradoxical to many of you that a representative of the Food and Drug Administration would be invited to appear on your program to discuss the subject of food fads and nutritional quackery in view of the unchallenged nutritional status your products have always enjoyed and their present abundant supply to the American people.

I am sure that some of you even resent the association of your products, and I am referring to butter, cheese and other dairy products, with the terms "food fads" and "nutritional quackery", since it is distasteful and abhorrent to you to think that the time will ever come when your products must be promoted on the basis of something other than their nutritional qualities.

Many of you who have come to listen are hopeful, I am sure, that I will tell you that we are going to do something about your competitors, associates and others who have been making disparaging and degrading comments about your products, while making exaggerated nutritional and therapeutic claims to encourage the purchase and consumption of substitutes. Whatever your feelings, and whatever you expect to hear, I am glad to be with you. I hope to give you a better understanding of our program against nutritional quackery

and food misinformation and to suggest how you can help us accomplish its objectives.

We start with the accepted fact that the American food supply is unsurpassed in volume, variety and nutritional value. Americans generally have to go out of their way, nutritionally speaking, to avoid being well nourished. Deficiency diseases in our population are now almost unknown, and overweight instead of underweight is one of our major public health problems.

Notwithstanding the abundance and quality of our food supply, consumers are being constantly barraged by exaggerated claims and misconceptions distributed not only by food faddists and nutritional quacks, but by some of our most respected food manufacturers.

The American consumer has become health conscious, diet conscious, weight conscious, vitamin conscious, mineral conscious, fat conscious and protein conscious, but he has limited knowledge to deal with these new "consciousnesses." He has been made aware of important nutritional factors and concepts, but his knowledge has not reached the point where he can distinguish between sound nutritional advice and nutritional nonsense. He hears the words vitamins, minerals, protein, unsaturates and so forth, so often that he feels much happier if he sees one or two of them on the label of any food he buys. In addition he is being constantly told that he must improve his diet with some type of "food supplement" if he is to enjoy good health. As a result, many consumers find it very difficult to make a rational choice of their food.

The consumer is being propagandized by "health food lecturers," and "health writers" like Lelord Kordel, Adolphus Hohensee, Carlton Fredericks, William L. Abt, Royal Lee, Gaylord Hauser, Dr. Crane, Dr. Taller, Dr. Jarvis, "Bob" Cummings, Dr. Allen E. Banik, Dr. H. Curtis Wood, Jr. and others; by newspaper, television and radio advertisements and announcements sponsored by scores of dietary food manufacturers and distributors; and by thousands of house-to-house salesmen of high-priced food supplements.

The technique of all these is to spread false ideas and half-truths and to undermine public confidence in the nutritional value of staple foods. They use a scare technique that capitalizes on the limited knowledge that consumers have about nutrition and their inability to distinguish between fact and fancy. Their stock in trade is the four great myths of nutrition: (1) all diseases are due to faulty diet;

(2) our basic foods are nutritionally inferior because our soils have become impoverished through long use and because chemical fertilizers have "poisoned" the land; (3) commercial food processing destroys the nutritive value of foods; (4) most Americans suffer from subclinical deficiencies that cause all the vague aches and pains, "that tired feeling," and so forth that affect human beings.

All these myths have been debunked scientifically and legally. There is no sound basis for any of them. Yet they are the foundation for most, if not all, the misinformation and quackery that is being perpetrated on the American public in the name of "nutritional science." They are the motivation for Americans to pay hundreds of millions of dollars annually for vitamin pills, food supplements, special formula food and nutritional nostrums of every description.

Food and Drug Commissioner Larrick summarized the problem in his talk to the National Congress on Medical Quackery last October when he said:

> The most widespread and expensive type of quackery in the United States today is the promotion of vitamin products, special dietary foods, and food supplements. Millions of consumers are being misled concerning their need for such products. Complicating this problem is a vast and growing "folklore" or "mythology" of nutrition which is being built up by pseudo-scientific literature in books, pamphlets and periodicals. As a result, millions of people are attempting self-medication for imaginary and real illnesses with a multitude of more or less irrational food items. Food quackery today can only be compared to the patent medicine craze which reached its height in the last century. Especially disturbing is the tendency shown by some big and hitherto respected food concerns to use quackery in their sales material.

The Food and Drug Administration is giving attention to this problem by enforcement and education. We concluded long ago that if we are to have any impact on this mockery of medical and nutritional science, we must do more than talk about the problem. We must devote our efforts to exposing the quacks through legal action and publicity. This is the foundation of our program.

On the regulatory front we are bringing scores of legal actions—seizures of misbranded products, prosecution of promoters, and injunctions to prohibit further distribution of violative products. I would like to review a few of these recent court actions to illustrate the scope and vigor of our regulatory program and the type of promotional schemes that are being used to induce consumers to buy dietary preparations for the treatment of every known and unknown disease condition. Some of these cases are still pending in the federal courts.

Nutri-Bio Food Supplements

The Nutri-Bio Corporation of Beverly Hills, California, has had phenomenal growth in a space of some three or four years. Using the chain letter technique of selling, the firm built a pyramid in the marketing of vitamin-mineral food supplements and of so-called protein tablets by 75,000 full and part-time door-to-door salesmen. Investigation disclosed that the literature of the firm misrepresented the significance of the articles for special dietary supplementation, but that sales had been sky-rocketing principally because the salesmen were grossly misrepresenting the products by books, such as "Bob" Cumming's *Keep Young and Vital,* and in oral sales spiels in customers' homes. Consumers were being induced to buy Nutri-Bio for the treatment and prevention of many serious diseases, including cancer, psoriasis, arthritis, diabetes, high blood pressure, heart disease, flu and others. Seizures resulted at Seattle, Washington, Tonowanda and Buffalo, New York, Washington, D. C., Charlotte, North Carolina, and Atlanta, Georgia.

The Nutri-Bio Corporation is attempting to revise its literature now and to devise a plan to control the representations of their door-to-door distributors. We shall be interested in seeing how well they succeed.

CDC Capsules

These initials stand for "Calories Don't Count", and identify a capsule containing about 912 mg. of safflower oil and 0.5 mg. vitamin B_6. It is vigorously promoted as a treatment for obesity by Code Vitamin and Pharmaceutical, Inc., Glen Cove, New York. The promotion is based on the theories of an obstetrician and gynecologist, Dr. Herman Taller, as set forth in his popular book *Calories Don't Count.* According to Dr. Taller, it is not the number of calories that is important in the treatment of obesity, but rather where the calories come from. He attributes some miraculous property to fats from vegetable sources to mobilize stored fat to produce what has been called a "washing out of adipose tissue". Consequently, he recommends almost unlimited amounts of vegetable oils, particularly safflower oil, special high linoleic acid fats and gluten foods. Incidentally, Dr. Taller recommends that cream be "scorned" absolutely but his section on diet formulas shows cream as an ingredient in his recommended Hollandaise sauce. He is kinder to cheese and says it can be eaten in unlimited amounts.

Dr. Philip L. White, Director of the Department of Foods and Nutrition of the American Medical Association in his review of Dr. Taller's book has this to say:

> . . . he has written a book that will rank high on the list representing nutrition nonsense and food quackery. . . .
>
> The title of the book is most unfortunate and misleading. Calories do Count.
>
> In summary, this book is a grave injustice to the intelligent public and can only result in considerable damage to the prestige of the medical profession, of which Dr. Taller is a member.

We seized a stock of CDC Capsules in January accompanied by Dr. Taller's book in which we charged the capsules were falsely represented as effective for the control of body weight without regard to the calorie intake and that they were effective in lowering the cholesterol level of the blood, for treating arteriosclerosis and heartburn, improving the complexion, increasing resistance to colds and sinus trouble, increasing sexual drive and for other purposes including heart disease. The case has not been adjudicated and the indications are that it will be contested.

From the recent advertisement that appeared in one of your Chicago papers for CDC Capsules, it is clear that the seizure action has not stopped the promotion of this product. As a matter of fact, Dr. Taller has started a "safflower oil binge" that is now sweeping the country.

How to deal with manias like this one that are stimulated by the writings of professional men is worthy of the most serious effort not only of the Food and Drug Administration but of all concerned with good nutrition and the public health.

Carlton Fredericks—"Self-Styled Nutritionist"

Carlton Fredericks is a "self-styled nutritionist" who has been broadcasting over about 50 radio stations in this country. He also publishes a diet book entitled, *Eat, Live and Be Merry,* and other pamphlets and booklets on health subjects. Mr. Fredericks' basic theory is that all ailments of mankind are due to faulty diet and devitalized foods, and all diseases can be successfully treated by taking vitamins and other food supplements. We have made two seizures of vitamin preparations based on misbrandings resulting from Mr. Fredericks' writings and his radio lectures. In addition to charges based on false nutritional and therapeutic claims, we also challenged his claim that he is "America's Foremost Nutritionist". Actually, he has no formal training or educational qualification as a nutritionist.

Royal Lee and Vitamin Products Company

Royal Lee, who for many years has been one of the leading sources of nutritional quackery in this country, has pleaded no contest in a criminal action at Milwaukee and is awaiting sentence for distributing misbranded vitamin and proprietary remedies. His Vitamin Products Company entered a similar plea and will be sentenced at the same time. These defendants have also consented to an injunction which will prohibit further distribution of more than 115 products claimed to be good for some 500 different diseases and conditions. The Lee products and literature have been distributed for years through health food stores and drugless practitioners throughout the country.

These current regulatory actions are but a few of the many that have been filed in recent months. But they do illustrate some of the techniques of promotion that are being used which result in widespread dissemination of false information.

We hope to step up our regulatory program and make it more effective by the assignment of more manpower and by better regulations. Being kind to the quacks is not a part of our thinking.

National Congress on Medical Quackery

Law enforcement, of course, is only part of the answer to quackery. Even more important is to help the public understand the facts about nutrition and to warn people against false claims and theories. This was the purpose of the National Congress on Quackery that was held in Washington last October. This Congress was sponsored by the American Medical Association and the Food and Drug Administration and represented a continuation of a joint public information and educational program that was started about two years ago by AMA, FDA and the National Better Business Bureau. This program has gained a great deal of support from organizations like the American Home Economics Association, the American Public Health Association, the American Dietetic Association, the Nutrition Foundation and scores of others. This program is very encouraging to the Food and Drug Administration because it has received such wide support not only from health organizations but from industry, educational organizations and institutions, and the press. It has impressed us with the fact that there are a great many others besides the government regulatory agencies who are interested in the problem of quackery and are able to help.

Our facilities are being expanded in the public information and educational areas in order to make our efforts more effective. We are confident that education of the public is our most powerful weapon against quackery and our best hope of dealing with the problem successfully. Enforcement and consumer education go hand-in-hand.

Now I am sure that most of you at this point are with us in this program because like sin everybody is against quackery. But I am equally sure that most of you are still wondering what this has to do with you. At the risk of hitting a few sore spots, I would like to try to bring this problem a little closer to home.

You will recall that toward the beginning I quoted Commissioner Larrick's statement before the Congress on Medical Quackery in which he said, "Especially disturbing is the tendency shown by some big and hitherto respected food concerns to use quackery in their sales material."

Quackery has some strange bed fellows. Whether it is practiced by house-to-house salesmen, writers of books, medical columnists, self-styled experts or the advertising organizations of food and drug manufacturers, it wears the same mantle—falsehoods, half-truths, fear, deceit—and capitalizes on the basic desire of people to trust and believe in matters involving their health. Quackery and misinformation delude those in good health into thinking they are ill or will become ill and those in poor health into thinking they will get well.

Does it come as a shock for me to tell you that reputable members of the food industry are contributing significantly to the problem of nutritional misinformation? We can cite case after case in which the quacks have attempted to justify their "curative" claims by citing similar claims made by food firms.

Isn't the advertising and promotional approach being used by some of our food manufacturers based on the same "hallmarks of quackery" used by the quacks? Among the claims they make are:

(1) disease and poor health are due to faulty diet;

(2) our basic foods are inferior and must be enriched or fortified;

(3) the nutritive value of processed foods has been destroyed;

(4) most Americans suffer from subclinical deficiencies;

(5) to reduce or gain weight special or unusual foods are necessary.

If you don't agree this is true, let me call your attention to some of the questionable statements and phrases that are now being widely used on food packages and in food advertising:

body building	builds strong teeth
bone strengthening	extra nourishing
energy producing	healthful
now enriched or now fortified	significantly greater in vitamin and minerals
provides health	rich in healthful vitamins
high nutrition	12 less calories per pat
less calories per bowlful	30 per cent more protein per spoonful
quick energy	

Advertising agencies refer to such claims as mere "puffery." We think they are false and misleading.

That food is clean, wholesome, attractive, nutritious, tasteful and reasonably priced is not enough.

Let me be a little more specific.

Vitamin and Mineral Claims

The sensible enrichment of some of our basic foods has the approval and support of nutritionists and public health officials. The wasteful, irrational addition of vitamins and minerals to foods merely for sales promotion is disapproved by all scientists and public health officials. The food industry is now carrying on a competitive battle of therapeutic claims based on the addition of vitamins and minerals to foods. The industry must accept its share of the blame for the "vitamania" being suffered by consumers, and the reaction that will occur.

In the meantime, we intend to give increasing attention to this area through enforcement. I am sure you have already heard of some of our actions in this field. For example, we made three seizures of a vitamin and mineral enriched sugar because of claims that it would produce and maintain health and vitality, prevent overweight, build beautiful teeth, and so forth.

We have within the last month seized shipments of four so-called "milk fortifiers," one of which was a "super" product, because the labels made claims such as "will promote healthy teeth and gum formation, resist infection, promote growth in children, sturdy bones, healthy blood, nerves and skin, and cause the blood and body cells to release energy." These are all competitive products and they bore remarkably similar labels.

We seized a shipment of "2 per cent skim milk" at Boise, Idaho, because of unwarranted claims based on the added vitamins and minerals.

There have been many other actions based on the irrational enrichment of foods and resulting claims. There will likely be many

more before some order comes out of this chaos. We hope that food manufacturers will adopt a more sensible approach to this problem and avoid the necessity of regulatory action.

"Low Calories," "High Nutrition—Low Calories," "High in Protein—Low in Calories," "For Weight Watchers," "Weight Control"

These are very popular terms being used on many food products whether or not they are appropriate. They are further evidence of the fierce competitive battle that is going on to influence consumers to buy. In most instances there is no sound nutritional basis for the claims.

This type of promotion is based on pure emotionalism and is not far removed from that used by the "health hucksters" we talked about earlier.

We are looking over the labels for food products bearing these types of claims and have already seized shipments of peanuts from two principal distributors because the labels stated "less calories" with subordinate statements as "not greasy," or "no oils or sugar used in processing." Again you will note that the claims were similar for these competitive products.

We have seized shipments of: calorie weight control products from a number of manufacturers because of exaggerated claims; candy labeled "low calorie"; popcorn labeled "real body building protein energy . . . surprisingly low in calories".

We also seized a shipment of olive oil represented as producing health, strength, long life and physical resistance to disease.

Dairy products are not entirely free from this type of promotion. We have noted an increasing tendency to promote various dairy products for reducing by using such statements as: "skim milk for that slim trim look," "low calorie creamed cottage cheese," "low calorie iced milk."

These statements can only confuse and mislead, since the average consumer has no basis on which to judge their meaning. They become meaningful only when there is a frame of reference that the consumer is familiar with. In other words, we believe that references to calories should be limited to an appropriate statement of the calorie content of the food and to nonmisleading comparisons with other foods that are used in a similar way in the ordinary diet.

Now this brings me pretty close to home as far as you are concerned. To meet the competitive challenge on the wave of reducing fads and other questionable promotions, we have been urged to permit the marketing of so-called "low calorie butter" and "low calorie oleomargarine." Some firms want to market "imitation butter" and "imitation oleomargarine." Totally aside from the fact that we do not believe there is any legal way to market such products under the present law, we think that these practices if permitted would simply add confusion to an already involved situation. We seriously question whether there is any real merit, nutritionally speaking, in these proposals. We would hope that the dairy industry would not pursue these overtures, since, if adopted, they would mean that there would be no standards for butter and oleomargarine that had any meaning. Surely the situation has not reached the point where you would want this to occur.

Before closing this rather long discussion, I would like to comment on one further problem and that is the misleading promotion of food products based on their fatty acid content. This is a classical example of the exploitation of the American consumer by some of our most respected food firms based on the most preliminary and presently unsupported scientific observations. Here is brinkmanship merchandizing at its best or perhaps we should say at its worst. We think the American people are being led to believe that it is an established fact that there is a cause and effect relationship between dietary fat and heart disease and are being encouraged to make major changes in the amount and type of fat in their diet. This is notwithstanding the fact that the National Research Council, the American Medical Association, the Public Health Service, and others have repeatedly stated that there is no reason for recommending a major change in the diet of the general population at this time. As late as February 28 of this year, Dr. White of the AMA in a talk before the National Association of Margarine Manufacturers here in Chicago summarized the current scientific thinking in this area as follows:

> Current research on fat metabolism has not changed the concept that a good diet is a balanced diet consisting of a variety of wholesome foods that provide all the required nutrients. And it is still true that a balanced diet in regard to fat will be supplied by eating a variety of foods from both animal and vegetable sources.

But the battle of polyunsaturates goes on and the consumer becomes more and more confused. Isn't this the type of setting that encourages strong governmental intervention?

The position of the Food and Drug Administration is set forth in our policy statement of December 10, 1959, which states that fats and oils represented for the treatment or prevention of heart and artery diseases will be considered misbranded under the Federal Food, Drug and Cosmetic Act. We believe we can support this position in court and, consequently, we are proceeding against all products where it can be shown that they are being represented for these purposes. But this is not the real problem, for such direct claims are not generally being made on food labels. Rather a variety of terms are being used which we believe are being interpreted to mean that the products are of value in the prevention or treatment of cardiovascular diseases. We intend to find out how consumers interpret such terms as "poly-unsaturated," "low in cholesterol," "made from golden corn oil," "double the unsaturation," "super unsaturated," "never hydrogenated" and similar statements. If consumers are being misled by these terms, we intend to take regulatory action.

We believe that the prevention and treatment of artery and heart disease is a medical problem for the medical experts. Laymen are not qualified to either recognize or treat such serious medical conditions. We do not believe that legal labeling can be designed for any food that recommends the article either directly or indirectly to the layman for the treatment of heart and artery disease.

Quackery means many things to many people. Whatever it means to you, we hope we can depend on you to help us control it.

Food fads come and go and come again. They are a poor substitute for sound nutritional education and wholesome food. As beguiling as they are in the competitive battle of the moment, they are not a satisfactory foundation on which to build a sound business with lasting consumer respect. [The End]

FALSE GERIATRIC CLAIMS FOR VITAMINS

Court action against a large quantity of Geriatric Vitamin Capsules was settled with a consent decree.

FDA charged in a seizure action filed in the federal district court at Grand Rapids, Michigan, that the capsules were misbranded under the Food, Drug and Cosmetic Act. The agency attacked false claims that the capsules are of special value to the aged and that they are good for treating and preventing mental depression, common colds, degenerative, cardiovascular and rheumatic diseases, diabetes, loss of appetite and other conditions. Other false claims, FDA said, included statements that the nutritional requirements of people over 40 are different from adults generally, that the capsules are of value for special dietary supplementation and therapeutic use and that they are a complete, balanced formula.

The FDA and Consumer Protection

By GEORGE P. LARRICK

Mr. Larrick Is Commissioner of Food and Drugs, United States Department of Health, Education and Welfare. He Presented This Paper at the Fifty-fifth Annual Convention of the National Canners Association in Bal Harbour, Florida on January 23, 1962.

THE ORGANIZATION of the National Canners Association in 1907 came hard on the heels of the passage of the Food and Drugs Act of 1906. At the time of its organization, the Association endorsed this law. This was the beginning of a cooperative effort between the canning industry and federal officials to protect the consumer through intelligent enforcement of food laws which is continuing today. The close association of your organization and ours was strengthened in 1913 when Doctor W. D. Bigelow and Doctor A. W. Bitting went from the United States Bureau of Chemistry, FDA's predecessor, to head the newly established research laboratories of the National Canners Association. Since we have had this long history of mutual concern about consumer protection, we thought it might be of interest to consider the organization, performance and relation to consumer protection of the phase of our work which is the grass roots contact of FDA and canners. This activity is factory inspection.

The inspection process as we know it today has developed during the past 23 years. The old Food and Drugs Act of 1906 did not contain a factory inspection provision. The result of the 1906 law was that those firms that had nothing to hide generally allowed our inspectors to enter their establishments and to make whatever inspection was necessary of manufacturing operations, formulas, and so forth. This proved beneficial to both government and industry. I am sure many of you recall the cooperative studies of tomato processing conducted by the late B. J. Howard of our laboratories and a number of canners. From such pioneering work came the mold counting procedure now used throughout the country to establish that tomato products are free from rot. But firms that had something to hide

would not permit factory inspection. Then in 1938 the Federal Food, Drug and Cosmetic Act was passed and it did make provision for factory inspection. However, the inspections of the late 1930's and 1940's were certainly unlike those of 1962.

In 1938 we were not concerned about food additives as we know them today. Color additives were treated as being safe in any quantity or not safe at all. We didn't have the great variety of agricultural pesticides which are now being employed. Industry hadn't begun to use many of the amazing processes which have done so much to advance food technology and improve food quality.

Filthy Factories

But many factories were dirty. Sanitation was a major problem throughout the food industry. Factory inspection was undoubtedly one of the most important stimuli exerted in improving sanitary conditions in food plants. As you well know, your association pioneered in the field of plant sanitation. As early as 1914, your committee on sanitation recommended a set of sanitary requirements for canneries; in 1923 you adopted a sanitary code; and through the years you have made important recommendations regarding proper cooks of various fruits and vegetables to safeguard the health of the consumer. You are to be congratulated for your leadership in this field. It is important to remember that it has been the enlightened areas of industry which have provided us with much basic knowledge as to how a job should be done, and could be done to the benefit of both the consumer and the processor.

Today the inspection situation is vastly different. Plant sanitation has improved dramatically. Industry and government working together have virtually eliminated the types of insanitation which can be detected by gross observation. But we now have a situation in which, because of the emergence of convenience foods that do not undergo thorough cooking in the home kitchen, bacteriological contamination has assumed much greater importance. We also have a greater responsibility in other areas of factory inspection. We have over 2,200 chemicals being used in 3,000 different ways as food additives. The law now permits toxic color additives to be used in safe amounts in foods. A vast array of agricultural poisons is being used to help the farmer produce bigger and better crops, often leaving residues on foods. Each of these new developments places grave re-

sponsibility on industry and on us: the responsibility for determining that potentially unsafe materials are being employed in food in strict compliance with the regulations designed to insure their safety.

The changes being made in the structure of food itself are tremendous. Fats are being broken down and rearranged. Starches are being modified so that they have properties more desirable to the food processor. Individual amino acids are being produced in the chemical plant and employed in foods. Industry is growing to keep pace with the population growth and with the food changes resulting from an expanding food technology.

We estimate there are over 100,000 establishments either producing, processing or handling commodities subject to our jurisdiction, of which approximately 90,000 deal with foods. We estimate that about 3,000 of these are canneries. Approximately 25 per cent of our total staff are inspectors who spend a sizeable percentage of their time making factory inspections. Considering the tremendous number and complex nature of the establishments we must cover with an inspection staff of only 652 men, it is obvious that some rather careful planning must be done to best utilize our facilities and obtain as broad coverage as possible. There are several criteria used in deciding just which firms to inspect in a given year. Some of these are: Was this firm in violation of the law when last inspected? What kind of history does the firm have regarding violations? How long has it been since the last inspection of this plant?

And, of course, situations arise which make it necessary to place special emphasis on a given segment of the industry because of some specific industry-wide practice. For example, we are currently making a nationwide investigation of the production of survival kits containing emergency rations and water for use in fall-out shelters.

However, even with the best planning we can develop, our inspectors are able to visit a firm on the average of only once in about four years. Yet while in the factory our inspectors are often able to best serve the consumer and industry by correcting potential violations of the law at their source.

In the year ending June 30, 1961, we brought over 900 legal actions in the food area but only 81 of these involved canned products. Fifty-one seizures of canned goods were made because of violations of sanitary requirements.

When the inspector visits your factory, he is charged with the responsibility of closely examining the firm's operations and obtaining

sufficient facts to enable the administrative officials of the Food and Drug Administration to determine if the firm is complying with the Food, Drug, and Cosmetic Act. Present law empowers our representatives to inspect all pertinent equipment, finished and unfinished materials, containers and their labeling. This law was enacted in 1953 to overcome a deficiency that was discovered in the earlier factory inspection provision of the 1938 Act.

Extent of Factory Inspection

When the remedial legislation was proposed in 1953 we believed the amendment should among other things authorize examination in the factory of formulas, complaint files, records showing that personnel in the factory are qualified to perform their assigned duties, and records of interstate shipment. During the passage of the bill a legislative history developed which cast doubt upon our authority to make complete inspection.

Consequently we have had to pursue our inspection activities under the shadow of questionable authority which sometimes reduces phases of our inspections to the ridiculous level of hide-and-seek games. Fortunately we have had the cooperation of most conscientious businessmen and organizations which has made our job more effective than it otherwise might have been. But there have been those individual firms and segments of industry which have retreated behind the letter of the law to the detriment of the consumer. Obviously it is the shady operator, the corner cutter who has the most to lose by allowing our inspectors full access in examining his operation. If we are able to make only a cursory examination of his plant, he thinks he might get by with something. He has a point, because it frequently is not possible in the modern food, drug, or cosmetic factory to make a sound determination as to the legality of a firm's operations simply by examining the building, the equipment, the raw materials, containers, labels, and those manufacturing operations that happen to be in process during the inspection. The inspector needs to examine the manufacturing formulas to determine that proper ingredients are being used in the proper amounts. For example, if a manufacturer is using a food additive, the inspector must determine if the additive is being used within the limits set for it.

Also, it is increasingly important for the food manufacturer who uses toxic chemicals as food additives to learn to employ the same type of control procedures that have been recognized as essential

for many years in the drug area. It is not good public health protection to allow food producers to use toxic materials in safe amounts, as Congress has done, without giving the government inspector the authority to determine that they are used properly. Therefore the inspector needs to examine the firm's own control records to determine what steps it employs to guard against errors.

Control records are also significant even if additives aren't being used. For example, canners have been cooperative in furnishing our inspectors with information about processing time. However, if they interpreted the factory inspection provision as some other industries have and refused to give food and drug inspectors information about processing times and similar control operations, this would significantly impair our ability to inspect the cannery adequately.

The need for examining the qualifications of plant employees is self-evident. The individual responsible for determining the quantities of toxic materials that go into foods must be trained to perform his operation properly. To make a complete inspection, the food and drug inspector must be able to determine that this employee is qualified to do his job.

New Legislation To Be Proposed

President Kennedy has announced he will recommend legislation which will strengthen the inspection provision of the Food and Drug laws. In his State of the Union Message on January 11, 1962, he said:

"To protect our consumers from the careless and the unscrupulous, I shall recommend improvements in the Food and Drug laws—strengthening inspection and standards, halting unsafe and worthless products, preventing misleading labels, and cracking down on the illicit sale of habit-forming drugs."

As our society becomes more complex, the evolution of technology requires more safeguards for the consumer. As much as we might admire the rugged individualist, when you have 90,000 firms dealing in over $82 billion worth of food each year, you can't have each going his own merry way. Processors who are hundreds of miles from the point at which their product will be consumed have to have standards of operation to live up to and somebody has to see that the processor does in fact live up to them. We believe that you and we together have to do the job the individual housewife would do if she were preparing a product in her own kitchen. And really the food plant is just an extension of the home kitchen. Since the housewife can't go several hundred miles or more to assure herself of the quality

of raw products used, the sanitary conditions of the commercial kitchen, the methods of handling and preparing the food, and the additives that are employed in its preparation, we are supposed to do this job for her.

Every year brings a greater use in the American home of prepared and convenience foods. With more and more of the food preparation done outside of the home kitchen, our responsibilities increase. The thoroughness of our factory inspections hinges on the possibilities for errors and the complexity of the manufacturing operations employed. We know that the responsible elements of the canning industry are just as interested as the Food and Drug Administration in having a fully effective factory inspection provision in the Food, Drug, and Cosmetic Act.

I would like also to mention one other area involving consumer protection which I belive is of interest particularly to you members who use oils and fats in your products. A little over two years ago we publicly stated our views with respect to claims being made for unsaturated fats in foods. Responsible scientists tell us this position is still sound. We are currently studying the labelings of some basic fat and oil products. If we obtain evidence that they bear claims which lead consumers to believe the products will prevent or cure circulatory diseases, we will take appropriate legal action.

The canning industry has pioneered in the development and passage of sound food legislation both at the state and federal levels. It has made great contributions not only in food processing but also in the field of food regulation. We are proud of the long-standing cooperative relationship existing between this industry and the government. We are sure this relationship will continue and be responsible for achieving even greater consumer protection in the future.

[The End]

Food Additives and Regulations

By JOHN L. HARVEY

Mr. Harvey Presented This Paper at the Food Industry Science School of Rutgers University on January 18, 1962. He Is Deputy Commissioner of the Food and Drug Administration.

THE FOOD ADDITIVES AMENDMENT to the Federal Food, Drug and Cosmetic Act was enacted in September, 1958 and represented the culmination of substantial Congressional interest in this important subject over a period of almost ten years. This amendment provides for control of food additives whether they be added directly and intentionally to the food or whether they become a part of the food indirectly through migration from machinery or packaging materials. Actually, these additives were subject to the law all along but the amendment makes it necessary that those responsible for the additive becoming a part of the food shall first establish their safety to the satisfaction of the Food and Drug Administration, which can then issue regulations authorizing their use.

I should point out perhaps that this law applies to both human and animal food and covers all substances or mixtures of substances which are not generally recognized as safe by experts qualified to evaluate them.

There are exemptions for the products which have prior sanctions for specific uses but this was merely to deal with those manufacturers who had come to us with adequate safety data before there was a law which required that they do so. In our opinion, this is an eminently fair provision. It applies to prior sanctions not only under the Food, Drug and Cosmetic Act but under the Meat Inspection and the Poultry Products Inspection Acts enforced by the United States Department of Agriculture.

This law started out with different effective dates. It was effective in March, 1959 for new products and in March, 1960 for substances in use prior to January 1, 1958, but in the latter case there was provision for individual exemptions for one year on a showing that the uses involved would present no undue hazard to the public health and that the exemptions were necessary.

When 1961 rolled around, it was obvious that further time was needed for testing for many of the products which had been granted these extensions. We proposed and actively supported legislation to authorize us to grant further extensions. This resulted in the enactment of such authorization so that, where the facts warrant and where there is no undue hazard to the public health, we have authority to extend the effective date for specific uses of additives for needed periods not beyond July 1, 1964.

We were in favor of this legislation because we thought it was the right thing to do but we have been rather bitterly criticized in some quarters on the charge that we were in favor of "lax enforcement" and the addition of poisons to our food supply. Notwithstanding, we still think we were right.

Introduction of General Regulations

Our first job after the law was enacted was to get out general regulations. We tried to set forth just what this law should be interpreted to cover. We spelled out how to go about petitioning for a food additive regulation and specified just how we would operate in considering and issuing regulations. In accordance with our usual procedure, we first published our regulations as proposals and invited comment from all concerned. We were most appreciative of many of the comments we received and by taking these into account, we made revisions which, in our opinion, resulted in a good set of regulations for the guidance of all concerned.

Our next endeavor was to try to make it as easy as possible for firms and individuals to decide for themselves whether or not they had any problem under this law. We published a proposed list of substances, almost 200, which, in our opinion, would be regarded by the experts as generally recognized as safe; but not relying solely upon our judgment, we circulated this to several hundred scientists throughout the country to get their views. Subsequently, we finalized the list with the omission of only a few items where the experts had questions about our classification.

I think it would be well to make clear that there is a real difference between "generally recognized as safe" and "safe." If the scientific community generally recognizes the product as safe, it is automatically exempt from this food additives law. On the other hand, if there is no such general recognition but the advocates of the proposed use of the substance are able to convince the scientists of the Food and Drug

Administration that the particular usage is, in fact, safe, then there is a basis for considering the issuance of an authorizing regulation under this amendment.

Our next step was to consider prior sanctions. We published in the *Federal Register* a few of the prior sanctioned items in the packaging field but then we ran into some difficulty and reluctantly concluded that we would not be in a position to publish all of the prior sanctions which had been issued over the years before the enactment of the 1958 amendment. There were two reasons for this. In the first place, these sanctions were not given with the idea that they would be part of a grandfather clause in a subsequent law and many of these could be located only by careful search of our files on a company-by-company basis. Secondly, many of the prior sanctions were given for specific formulations and to publish these could well result in our revealing trade secrets which were supplied to us in confidence.

Therefore, as far as prior sanctions are concerned, the best we can do is to state to inquirers that if they believe they have a substance for a use covered by a prior sanction and need confirmation, all they need to do is to advise us of the information about their product, its usage, and the name of the firm to whom they believe a prior sanction was given. If we find that their product is identical with one covered by a prior sanction, we will so advise and thus, of course, the prior sanction will apply there as well.

I must caution, however, that we must construe prior sanctions very strictly and if a sanction was given for a specific formulation and any change has been made in that formulation in the interim, the prior sanction obviously could not apply to the new product.

Responses to Regulations

Having issued our regulations GRAS lists (with some later additions) and the limited prior sanction list, we geared ourselves to accept and deal with petitions for the many food additives which we were quite sure were covered by the law. To our amazement, we were not flooded with petitions as we had expected. Instead, we were flooded with inquiries from all sources. We received a tremendous volume of correspondence asking questions about this new food additive law. Some of these could be answered merely by reference to the regulations but most dealt with the question of "Here is my product. Here is how I use it. Is it a food additive?"

Where the additive was added directly to food, this presented a fairly simple problem. Where the substance was used in a packaging or equipment item, however, the answer was not quite so simple. Our scientists had devised some extraction tests using solvents which would simulate the action of various food ingredients and we suggested that where there was some doubt, that these tests be applied by the manufacturer to determine the facts.

Of course, we did get our share of inquiries which might be placed in the "silly" category which presented no difficulty in answering, except to find the time. I have in mind one where we were asked about the food additive status of an adhesive used exclusively to apply labels to the outsides of hermetically sealed cans. We had no difficulty in telling the inquirer that he had nothing at all to worry about so far as this law was concerned.

After we distributed thousands of copies of the methods for determining whether there was migration of components of packaging and machinery items to food, the avalanche of mail started again. This time it was more complicated in that we were supplied with the results of these tests and requests for our opinion as to whether or not we agreed that there was a food additive problem involved. The headaches really began in those cases where a review of the extraction data led us to conclude that there was no migration. Without too much foresight, I'm afraid, we began to write letters in answer to these inquiries in which we agreed, in some cases, that the data showed no food additive implications. It wasn't long, however, before we found that our letters were being photocopied and used for sales purposes, in some cases on the basis of "We have FDA approval for our products and your present supplier doesn't, so why don't you buy from us?" This started a chain reaction and even though many firms had taken us at our word and had made up their own minds on the basis of good data that they did not have a food additive problem, they found that they were at a disadvantage because they didn't have "the letter."

We came to the conclusion that we had opened Pandora's box and had better find a way to close it before the situation got completely out of hand. We therefore re-evaluated our position after consultation with our legal counsel and came to the conclusion that basically, if there was enough reason to run extraction studies on packaging or equipment materials, why shouldn't it be concluded that it would be reasonable to expect that the substances involved would,

in fact, become a part of the food? Since the law refers to "reasonably to be expected" we then began to advise those who asked that we were not in a position to give them a letter which would absolve their product from any responsibility from under the Food Additives Amendment but instead suggested that they file petitions. That is the present status of this item.

Requests for Extensions

Going back, at just about the March, 1960 effective date, we received a rash of requests for extensions and during the first six months of 1960, we issued formal extensions to March, 1961 covering some 3,000 uses of direct and indirect additives. At the same time, we did our best at every appearance we made before industry groups to point out that the granting of an extension was only the first step down the road to compliance and that as the law then stood, regulations would have to be in effect by March, 1961 if the particular product was to continue to be used after the final effective date. Somehow, we just didn't get the message across. It wasn't until early 1961 that petitions began to come in in quantity. Particularly in the field of packaging materials it was quite apparent that with our limited staff we couldn't even process and evaluate all of the petitions we had then and it was for that reason that we proposed additional time as I mentioned earlier.

We did administratively continue all previous extensions to September 1, 1961, meanwhile considering requests for these further extensions. Some we had to turn down because they did not meet the statutory provisions of the law which, among other things, required that you had to have done something about ascertaining the status of this product a year earlier and to have pursued the matter in the interim. Sometimes we had to turn down requests because the data was inadequate to enable us to conclude that the substances could be used without undue hazard.

While the law provides for extensions not to exceed July 1, 1964, there is nothing automatic about this date. In each case, we require the request to detail the time that is necessary and the extension is then given a time limit with a requirement that any extension beyond January 1, 1962, will require a progress report at six-month intervals starting this month. This is an important condition of the extension

and we will have no basis for doing other than cancel any extension where a satisfactory progress report is not received as required by the order.

If you are interested in statistics, so far we have granted 765 current extensions in the direct additive field and 1,152 current extensions in the indirect additive field. Of the "direct" extensions over 500 are in the flavoring field.

In the matter of regulations, just what have we accomplished to date? We have received 664 petitions for food additive regulations and of these we were unable to file 253. There are a number of reasons for these refusals. The simplest involves those which requested food additive regulations for substances which were not food additives, usually because their uses were in the generally recognized as safe category. The major reason, however, was that we found the petitions to be incomplete. In this category, we did not receive the necessary pharmacological data, the necessary technical information including methodology and, in some cases, there was no showing of the physical or technical effect of the particular additives. In a few cases, we had to reject the petitions because they referred to substances by trade names and we just didn't know precisely what substances should be evaluated.

Going back to statistics again, we have issued regulations (and amendments) in the following categories: 117 covering direct additives to human food; 41 covering direct additives to animal food; 33 covering packaging or equipment components; 3 covering the use of radiation.

The fact that some of the regulations have already been amended several times is to me most important. It demonstrates that these food additive regulations are not static documents and that they can be amended quite readily where there is adequate data to justify the changes which are requested.

The law provides that a decision on a petition shall be made preferably within 90 days, but not later than 180 days after the date of filing. I have to admit that we have been faced with some petitions where we just couldn't finish the job in the 180 day limit, try as we might. I can assure you that this had not been due to any "don't care" attitude on our part but has been due principally to our inability to make available a sufficient number of qualified people in the chemical and pharmacological areas to evaluate these petitions and make recommendations to the Commissioner's office.

We have the positions available, but we don't have the people and we are having real trouble in trying to fill these vacancies. I didn't came to this meeting with the idea of acting as a recruiting officer but if you know of any qualified chemists, biochemists, or pharmacologists who might be interested in working for the Food and Drug Administration, I sincerely urge that you refer them to us.

No discussions of the Food Additives Amendment would be complete without some reference to the Delaney Clause which states that we may not issue a regulation for the safe use of any food additive which has been found to induce cancer when ingested by man or animal or found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. This clause has engendered a great deal of controversy. But except perhaps in the area of animal feeds, which presents a special problem, it doesn't seem as though food manufacturers generally need have a great deal of concern about it.

Certainly, no manufacturer wants to add to his food products any ingredient which has been shown to cause cancer. We hear a great deal about the possibility that these cancer producers may have a threshold level below which they do not act to cause cancer. When you poll the scientists, however, even those who hold to this view, they come up with the comment that, of course, they don't know where this threshold level is for any specific chemical.

Under the circumstances, arguments about the Delaney Clause become rather academic. As far as the Food and Drug Administration is concerned, we propose to enforce this law as it is written, including the Delaney Clause, and if ever there is a sound basis for changing it, we are sure the Congress will give every consideration to such a proposal.

Regulatory-wise, our inspectors are checking for food additives in every food inspection operation they conduct and our laboratories are on the alert for food additive problems in the examination of both domestic and imported products. So far, we have made a few seizures in the food additives field, but have yet to institute criminal prosecutions. The seizures included mineral oil offered for food use, biscuits with added mineral oil, high inorganic bromide residues resulting from fumigation of flour and vitamin products containing unsafe amounts of folic acid.

Change in Industry's Attitude

We believe that there has been a marked change in industry attitudes about the Food Additives Amendment between 1958 and the present time. Now that industry has become knowledgeable about this law and understands how it operates, we no longer encounter a "fear" attitude. Similarly, there was a time when some considered the term "food additive" as a term of approbation when applied to their product. Now, however, we find that there is a recognition that the existence of an authorizing regulation gives a product a stature it did not have earlier. The regulation is there for all to see and to understand that it could not have been granted without adequate evidence of safety, a showing of physical or technical effect and, where a tolerance is involved, a suitable laboratory method available to enable enforcement of that tolerance.

This attitude has resulted in requests we are now getting for the establishment of formal food additive regulations to cover prior sanctioned uses so that these too will be out in the open for all to see.

We in the Food and Drug Administration thing that this is a good law. It is in the public interest and in the interest of manufacturers and distributors alike. If you have an additive that meets the test of the law, it can be authorized. If, however, the additive doesn't meet the test set forth therein, it shouldn't be considered for use in foods at all.

As for those of you who are actually manufacturing basic components of foods, machinery, or packaging materials, I would assume that there is little that needs to be said about your responsibilities in this area. Many of you, however, are not in that particular end of industry but rather are engaged in producing and marketing finished food products. I recommend that if any of you have not already done so, it would be highly in order for you to take a very careful inventory of every item in use either as a component of foods, as packaging material or machinery item. It is your obligation to be sure that the food you market does not contain a food additive the use of which is not covered by an appropriate regulation or, for the time being at least, an extension of the effective date of the statute.

Presumably, many of the questions which such a survey would raise could be answered definitively by your suppliers. But certainly if there is any question where you believe that the Food and Drug Administration's views can be of assistance, we will be very glad to have your inquiry.

While I am on this subject, I would like to comment on a speech delivered by an industry representative at the Food Law Institute conference held in Washington last November. This man told about his initial reaction to the Food Additives Amendment and the checking that he instituted in his own business to determine just how his firm stood in the light of the requirements of the amendment. While he stated that he did find some things that needed to be done in order to avoid conflict, he was quite fullsome in his remarks about the value of his investigation to his firm's over-all operations. It was obvious that this thorough check had disclosed a number of procedures which had been instituted for some special purpose and then had been perpetuated without good reason. He expressed the conclusion that this careful look-see at the firm's operations had given him a sound basis for revising operations to put out a better product at a lower cost.

Color Additive Amendments

Before closing I would like to discuss briefly the Color Additive Amendments of July 12, 1960. Prior to these amendments, the Food, Drug and Cosmetic Act provided only for the listing of *harmless* coal-tar colors in foods, drugs, and cosmetics. The Food and Drug Administration took the position that "harmless" meant harmless in *any* amount and that the law would not permit us to list colors for use in limited amounts even though these lesser amounts were safe. In a series of court actions the Supreme Court upheld this position. As a result, there was considerable agitation to amend the law to change this restriction and after conferences with industry, Congressional hearings and changes in a departmental bill, the Color Additive Amendments were passed.

The amendments consist of two sections. This first, while similar to the Food Additives Amendment, is at once both broader and more restrictive. It is more restrictive in that it applies only to colors. It is broader in that it covers the addition of colors not only to foods but also to drugs and cosmetics. A color used in foods comes under this law and not the Food Additives Amendment. *All* colors, those derived from vegetable sources as well as inorganic pigments are regulated, not just coal-tar colors. As with food additives, a color must be shown to be safe by adequate pharmacological testing. Specifications, methods of manufacture and needed methods of analysis both for the color itself and for determining it in foods, drugs or cosmetics must be submitted.

The law contains a Delaney Clause about cancer-producing colors. As in the Food Additives Amendment, generally a petition must be

submitted and a regulation authorizing use must issue. The batch certification principle continues except that the Commissioner may, by regulation, exempt a color from batch certification if consistent with the public health. The law requires that the cost of listing and certification shall be borne by fees. The listing of a food color, for example, requires a fee which has been tentatively set at $3,000.

The second section of the amendment is concerned with a transitional period. Recognizing that many colors would require extensive and lengthy pharmacological testing, Congress provided that for a two and one-half year period after the passage of the law, colors would be "provisionally" listed if consistent with the public health. Essentially this two and one-half year period is a "grace" period. All "coal-tar" colors listed and certifiable as of the date of enactment were provisionally listed provided at least one batch had actually been certified. All colors which were not previously subject to the certification section of the Act—and this means all non-coal-tar colors—are also deemed provisionally listed for uses formerly employed. This transitional section of the law authorizes removal of color additives from provisional listing if necessary to protect the public health and imposition of temporary limitations. Thus under this last provision mentioned, the Food and Drug Administration has provisionally listed a number of coal-tar colors for use in lipsticks provided not more than 6 per cent of total dye is in a lipstick.

Thus far, only one regulation permanently listing a color additive has issued. There have been several petitions for others but the information submitted has been inadequate and the petitions were not filed. Less than a year remains now for permanent listing of color additives. While the transitional section permits extension of the effective date (January 12, 1963) it is not contemplated that extensions will be granted on an over-all basis.

Extensions may be granted where evidence is submitted that the nature of the studies—animal testing for example—were such that it was physically impossible to complete them prior to the effective date.

The Food and Drug Administration proposes to administer both of these amendments to insure the best protection possible to the consuming public. From the standpoint of the end objective, we know that industry and government are united in desiring that the foods, drugs, and cosmetics marketed in this country shall be as safe as it is humanly possible to make them. **[The End]**

International Aspects of Food and Drug Legislation– A Selected Bibliography

Compiled by JULIUS G. ZIMMERMAN

Mr. Zimmerman Is Editor of Foreign Law for the FOOD DRUG COSMETIC LAW JOURNAL. The Following Is a Selected Bibliography of Publications in the English Language Which Accompanied a Lecture by Mr. Zimmerman at the New York University School of Law on March 27, 1962.

Recommended Reading from the *Food Drug Cosmetic Law Journal*

Title and Author	Issue	Pages
1. "The Food, Drug and Cosmetic Law of Latin America," by Julius G. Zimmerman.	November, 1954	655-673
2. "Food Legislation in Sweden," by Ernst Abramson.	January, 1955	5-19
3. "International Aspects of Food and Drug Legislation," by Julius G. Zimmerman.	July, 1957	402-429
4. "International Conference on Food Additives in London on July 26, 1957," Special Issue of JOURNAL.	August, 1957	455-528
5. "Legal Research Problems in Latin-American Food and Drug Law," by Julius G. Zimmerman.	November, 1957	683-689
6. "Latin American Drug Laws," by Victor C. Folsom.	March, 1958	165-171
7. "Codex Alimentarius Europaeus," by C. R. Shabetai.	June, 1958	343-349

Title and Author	Issue	Pages
8. "Mexican Regulation on Food Additives of Jan. 21, 1958," (Translation of Text).	June, 1958	353-379
9. "Report of Progress in Drafting the 'Single Convention', a Proposed Codification of the Multilateral Treaty Law on Narcotic Drugs," by H. J. Anslinger.	November, 1958	692-697
10. "Progress of Foreign Food Law," by Julius G. Zimmerman.	March, 1959	189-209
11. "Food Standards in England and Wales," by M. Compton.	June, 1959	361-376
12. "The New German Law on Food Additives," (Includes complete text of German Food Law Act, as amended on Dec. 21, 1958), by Hedwig Jochmus.	July, 1959	431-450
13. "The Importance of Uniform Legislation for the American Nations in the Field of Food Products," by Jorge E. O'Farrell.	July, 1959	451-457
14. "Necessity of Promoting Specialized Studies of the Food, Drug and Cosmetic Law in Latin America," by Enrique E. Bledel.	July, 1959	458-467
15. "Observations on the Drug and Cosmetic Laws of Latin America," by Victor C. Folsom.	July, 1959	468-479
16. "Food Additives Control in Canada," by Robert E. Curran.	February, 1960	108-116
17. "French Food Legislation," by Henry Francois Dupont.	March, 1960	165-195
18. "Foreign Law Comment," (Germany—Regulations on Food Additives), by Julius G. Zimmerman.	April, 1960	280-284
19. "Food Additives Control in Canada," by L. I. Pugsley.	August, 1960	487-517

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20. "Latin American Food Code," (1960 Edition) Introduction by Carlos A. Grau and Index.	October, 1960	678-688
21. "British Pure Food Centenary 1960," Special Issue of JOURNAL.	November, 1960	695-736
22. "Recent European Food Law Developments," by Franklin M. Depew.	December, 1960	817-822
23. "Latin American Food Code," (1960 Edition) Chapter IV—Utensils, Receptacles, Containers, Wrappers, Machinery and Accessories.	February, 1961	121-126
24. "Report on the Sixth Symposium on Foreign Matters in Food," by Ernst Abramson.	February, 1961	127-128
25. "The Need for Uniformity in Food Legislation," by Franklin M. Depew.	March, 1961	169-176
26. "Control of the Use of Food Additives in the United Kingdom," by Alan G. Kitchell.	March, 1961	177-183
27. "The Single Convention for Narcotic Drugs," by Robert W. Gregg.	April, 1961	187-208
28. "Latin American Food Code," (1960 Edition) Chapter X—Sugar and Sugar Products.	May, 1961	297-311
29. "The European Food Code," by Edmund Forschbach.	June, 1961	317-320
30. "Health and Food Legislation in Mexico," by Rafael Illescas Frisbie and Judith Gomez Farias.	September, 1961	537-548
31. "Latin American Food Code," (1960 Edition) Chapter XVI—Correctives and Improving Agents (Additives).	November, 1961	641-677
32. "Joint FAO/WHO Program on Food Standards," by Ernst Abramson.	February, 1962	131-134

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International Aspects—Items 3, 4, 7, 9, 10, 13, 22, 23, 24, 25, 27, 29, 32.

United Nations and Its Specialized Agencies FAO and WHO—Items 3, 9, 10 (See also items listed under heading 27, 29, 32 "Standard Reference Material").

Narcotic Drugs—Single Convention—Items 9 and 27.

Latin American Food, Drug and Cosmetic Laws and Latin American Food Code—Items 1, 3, 5, 6, 8, 10, 13, 14, 15, 20, 23, 28, 31.

Europe and European Food Code—Items 2, 3, 4, 7, 10, 22, 24, 29, 32.

Food Additives—Items 3, 4, 8, 10, 12, 16, 18, 19, 24, 26, 31 (see also items listed under heading "Standard Reference Material").

Canada—Items 16, 19.

France—Item 17.

Germany—Items 12, 18.

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United Kingdom—Items 11, 21, 26.

Standard Reference Material

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"International Digest of Health Legislation," quarterly published by World Health Organization (WHO) in Geneva.

"Food and Agricultural Legislation," quarterly published by the Food and Agriculture Organization (FAO) in Rome.

World Health Organization: "Technical Report Series" (individually numbered pamphlets):

No. 107 "Joint FAO/WHO Conference on Food Additives," (September, 1955);

No. 129 "General Principles Governing the Use of Food Additives," (First Report of the Joint FAO/WHO Expert Committee on Food Additives, 1957);

No. 144 "Procedures for the Testing of Intentional Food Additives to Establish Their Safety for Use," (Second Report of the Joint FOA/WHO Expert Committee on Food Additives, 1958);

No. 220 "Evaluation of the Carcinogenic Hazards of Food Additives," (Fifth Report of the Joint FOA/WHO Expert Committee on Food Additives, 1961).

Note: The following reports of the Joint Committee have not as yet been published in printed form:

Third Report: "Specifications for Identity and Purity of Food Additives (Antimicrobial Preservatives and Antioxidants)." Part 1 of this report was quoted by Dr. B. Oser in the September, 1959 issue of the FOOD DRUG COSMETIC LAW JOURNAL.

Fourth Report: "Specifications for Identity and Purity of Food Additives (Food Colors)."

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FAO Food Additive Control Series:

No. 1. "Food Additive Control in Canada, 1959"

No. 2. "Food Additive Control in the United Kingdom, 1960"

No. 3. "Food Additive Control in the Netherlands, 1961"

No. 4. "Food Additive Control in Australia, 1961"

No. 5. "Food Additive Control in Denmark, 1961"

"Yearbook of International Organizations," Seventh Edition 1958-1959, published by Union of International Associations in Brussels.

(Note: All the U. N. publications may be obtained from Columbia University Press, International Documents Service, 2960 Broadway, New York 27, N. Y., except "Everyman's United Nations" and the "Yearbook of International Organizations" which may be purchased at the United Nations bookstore in the General Assembly building.)

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

March Drug and Device Seizures Report.—Twenty-nine actions were instituted in February against misbranded and adulterated drugs and devices. Fourteen products, mostly dietary supplements, were charged with false and misleading claims such as promotion of appetite and "utilization of fat to lower blood cholesterol"; seven drugs and medicated feeds were of substandard quality, two were repacked physicians' samples without the labeling required by law, two failed to bear adequate directions for use, three injectables were marketed without new-drug clearance, sulfa tablets carried no prescription drug statement.

Other seizures included a cosmetic hair preparation which was counterfeit. Soldering salts containing a highly irritating and corrosive substance failed to bear warning labeling as required by the Federal Hazardous Substances Labeling Act.

Food Seizures.—Four hundred tons of contaminated food were seized in 51 federal court actions during February. Of this total, 39 tons were seized on charges that they involved nonpermitted pesticide residues, such as mercurial compounds and DDT. Excessive folic acid and deficiency in vitamins from the potencies declared on the labels were charged in seizures of nine nutritional supplements.

Among the largest seizures of filthy and decomposed foods were 280 tons of rodent-infested wheat; 23 tons of moldy, infested, or otherwise unfit nuts of various types; 18 tons of rice and 12 tons of flour held under insanitary conditions; and 6 tons of bacteria-contaminated frozen, breaded shrimps.

Nine seizures, involving 347 tons, were made of egg noodles deficient in egg content required by official food standards. Other substandard foods seized were peaches packed in lighter sirup than labeled, and substandard canned peas not labeled as such. Short weight was charged in shipments of pizza, popcorn, wild strawberry preserves and pecans. Failure to bear required labeling or its presence in too inconspicuous a manner to be readily found and read by purchasers was charged in eight seizures. In all, 28 seizures were made to protect consumers' pocketbooks.

Voluntary Actions by Industry.—The food and drug industries took 124 voluntary actions to protect the public from unfit products.

According to reports received last month approximately 80 tons of adulterated food were destroyed or converted to feed (73 actions), adulterated drugs valued at $235,341 were withdrawn from the market (31 actions), and the actual or estimated costs of voluntary plant improvements amounted to nearly $243,000 (20 actions).

A Georgia vegetable oil company started building a new seed house at

a cost of $151,220 after an inspection of this firm revealed the old building to be rodent-infested.

Another large investment was reported by a bread company in Tennessee whose flour handling systems showed severe insect infestation. At a cost of $50,000 this firm converted its old-fashioned equipment into a pneumatic system. A new sifter and vacuum cleaner were added and old conveyors and bins were replaced to improve sanitary handling of products.

A Massachusetts manufacturer of a mouthwash ordered the destruction of $32,877 worth of this merchandise after a color used in the product was taken off the list of permissable colors; part of the lots had been manufactured and packaged before the official cut-off date.

A drugstore in Arizona voluntarily destroyed $10,300 worth of fire-damaged drugs, cosmetics and devices.

"New Drugs" Without Safety Clearance.—Four drug products have been seized on charges that they were "new drugs" for which no safety clearance from FDA had been obtained as required by the new drug section of the Food, Drug and Cosmetic Act. The Act controls the safety of new drugs by prohibiting sale until safety has been established to the satisfaction of the Food and Drug Administration. Seized were:

"Reticulose Lipoprotein-Nucleic Acid Complex", manufactured by Chemico Laboratories, Inc., Miami, Florida, a sterile, intra-muscular, subcutaneous solution promoted for the treatment of herpetic diseases, infectious hepatitis, upper respiratory viral infections, mumps, orchitis, infectious mononucleosis, influenza, Asian influenza, generalized vaccinia and encephalitis;

"Expectogen," manufactured by E. W. Heun Company, St. Louis, Missouri, for King Pharmaceutical Company, Inc., Montgomery, Alabama, containing dextro-methorphan hydrobromide, chlorpheniramine maleate, potassium guaiacol sulfonate, ammonium chloride, tartar emetic, and chloroform, promoted for relief of coughs due to colds;

"Nepco-Gap Ampuls," manufactured by New England Pharmacal Company, Taylor, Michigan, an intravenous enzyme (guanido-amino-peptidas) preparation said to have been distributed only for investigational uses, but not in compliance with regulations applicable to new drugs for investigational use.

"Chymtrypsin Injection," manufactured by Injectable Pharmacal Company, Los Angeles, an enzymatic drug in aqueous solution, promoted for treatment of circulatory disorder, acute inflammation, bursitis, arthritis, hematoma in surgery, edema in dental surgery.

"Bennie" Peddlers Prosecuted Third Time.—Robert Lee Clure and Mildred Clure, man and wife team in the illegal sale of amphetamine drugs, pleaded guilty and have been sentenced for the third time for their spurious activities.

Judge L. Richardson Preyer of the United States District Court in Greensboro, North Carolina sentenced Robert Lee Clure to one year imprisonment to begin upon the completion of the three year sentence he is now serving for a previous conviction. His wife, Mildred, was sentenced to one year, which was suspended, fined $1,000 and placed on probation for five years.

The Clures have been prosecuted in three federal courts for their participation in a ring engaged in the illegal amphetamine drug traffic in the southeastern states. Capsules of the drug, called "bennies" or "co-pilots" by truck drivers, have the effect of keeping the user awake beyond his physical and mental endurance. Amphetamine drugs may be sold legally by prescription only. The Clures were peddling large quantities of the drugs to truck stops and filling stations where it was being resold to truck drivers.

The Clures have been fined a total of $21,000 in the three cases against them. Robert Lee Clure has been sentenced to a total of four years in jail with probation and Mildred Clure has been placed on probation.

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