VOL. 17, NO. 2 FEBRUARY 1962

Food Drug Cosmetic Law JOURNAL

This Issue Contains the Concluding Papers from the 1961 FDA-FLI Conference: The Federal Hazardous Substances Labeling Act . . . John A. Zapp, Jr.; Fallout and Our Food Supply . . . S. Allan Lough; Consumer Education in the Food and Drug Field . . . Edith H. Sherrard. Addresses from the New York State Bar Association Section on Food, Drug and Cosmetic Law Are Also Presented: Food Additives and Hazardous Substances . . . John L. Harvey; The Packaging and Labeling Hearings . . . S. Jerry Cohen.

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

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

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

February, 1952
Volume 17 • Number 2

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . February, 1962

VOLUME 17 NUMBER 2

Printed in United States of America

REPORTS

TO THE READER

About This Issue.—The concluding papers of the 1961 Joint National Conference of the Food and Drug Administration and The Food Law Institute, Inc., are published in this issue of the JOURNAL.

In the article on the Federal Hazardous Substances Labeling Act, the author *John A. Zapp, Jr.,* suggests that if industry and government would work together as associates rather than as adversaries, both would benefit. He reviews the legislative history of this new act and points out that industry played an active role before this particular labeling act was passed. He feels that now the active role of industry has been changed to one of being regulated rather than one of working with the government. Mr. Zapp, Director, Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours and Company, explains his ideas on this topic and offers suggestions to improve the situation. This interesting and informative article appears on page 104.

The Assistant Director for Radiological Physics, Division of Biology and Medicine of the Atomic Energy Commission, *S. Allan Lough,* offers an article on a subject which has provoked widespread comment in the past few months. The possible effects of radioactive fallout on our food supply concerns each and every human being. Mr. Lough explains the situation which has arisen as a result of the explosion of nuclear weapons. Of the many problems produced, the fallout of strontium 90 and cesium 137 are of chief dietary concern. He concludes by saying: "Our concern about fission product deposition is justified, however, for it has led us to study the problem thoroughly and has permitted us to understand rather well the extent of the influence which this new component in our environment might exert under the more severe conditions which would be associated with a large-scale release of these radioactive materials." This article appears on page 116.

The last of the papers presented at the FDA-FLI conference was that of *Edith H. Sherrard,* staff associate, Social and Economic Issues, American Association of University Women. Her article, which begins on page 122 explains that organization's program to educate consumers in the food and drug field. In discussing this program, she says that "we do not relieve industry of responsibility for achieving a large part of the new threshold of understanding. We do not diminish the role of government. We only say that in addition to everything else, the consumer herself has to find out about the changes going on in her buying world—not as an expert but as one who lives in that world —and that is the orientation for our consumer program." She asks the aid of both industry and government in carrying out her organization's planned projects.

The Associate Editor for Europe of the FOOD, DRUG, COSMETIC LAW JOURNAL, *Dr. Ernst Abramson,* reports on the 1961 FAO-WHO Food Standard Conference which was held in Rome on November 23. This report is significant because it marks the combined efforts of the Food and Agriculture Organization and the World Health Organization to establish an International Food Code which will supersede the European Food Code. It aims "at simplifying and integrating food standards work now carried on by many international organizations and at providing an effective mechanism for obtaining government acceptances of these standards." Dr. Abramson's report is found on page 131.

The seventeenth annual meeting of the New York State Bar Association Section on Food, Drug and Cosmetic Law was held on January 24 in New York City. A summary of the proceedings by *Chairman Franklin M. Depew* is found elsewhere in this JOURNAL. We are pleased to present two of the papers that were delivered at this meeting.

The Deputy Commissioner of the Food and Drug Administration, *John L. Harvey,* points out the recent developments in the food additive and hazardous substances fields. He notes "that the problem of evaluating food additives and getting out the necessary regulations was grossly underestimated both by industry and the Food and Drug Administration, and this is especially true in the area of the so-called indirect additives. We have had problems in this area and so has industry. I should pay tribute to the patience and understanding of the many industry groups and individuals who have been involved in this work." In his opinion, the Food Additives Amendment "is a splendid law. It is working, and we want to make it work better, so that the American consumer may continue to have justifiable confidence in the safety and integrity of our food supply." In regard to the Federal Hazardous Substances Labeling Act, Mr. Harvey clarifies the areas of coverage. He feels that this act is a big step toward rapidly reducing injury and illness caused by accidental exposure to household aids. This article starts on page 135.

S. Jerry Cohen, Counsel for the Senate Judiciary Committee's Antitrust and Monopoly Subcommittee on Packaging and Labeling of Food and Other Consumer Products, explains the problem of getting essential information to the consumer and the manner in which the hearings are being conducted. In his article, which begins on page 143, he states that the committee does not intend "to the stampeded into hasty or ill-conceived legislation. On the other hand, we are not prepared to accept status quo." In concluding, Mr. Cohen declares that "we hope to do a legislative job that will benefit all and shackle none; that will be definitive yet flexible; that will simplify, rather than make more complex."

In a talk before a district meeting of the American Association of Colleges of Pharmacy and National Association of Boards of Pharmacy, *M. R. Stephens* outlines the course of action for the pharmacist and the regulatory official to follow in their efforts to ensure the integrity of the national drug supply. Today the cost of drugs represents 20 per cent of the total cost for medical care in the United States. The author maintains that it is the pharmacist's responsibility to see to it that the drugs as manufactured and delivered to him are honestly and informatively labeled and of unquestioned composition. The drug must also be safeguarded until it reaches the user's hands. Mr. Stephens, who is director of the Bureau of Enforcement in the Food and Drug Administration, is concerned about the counterfeit drug racket and the illegal use of physician's samples. He believes that better regulatory tools and an awareness by the courts of the serious health hazard involved in these illegal actions are essential if the integrity of our nation's drug supply is to be assured. This paper is presented on page 148.

Charles G. Durbin, Veterinary Medical Director of the Division of Veterinary

Medicine in the Food and Drug Administration, discusses the problems that face the feed industry, the farmer and the FDA under the Federal Food, Drug and Cosmetic Act. In regard to the act, he observes that it is a protective law which forbids interstate commerce in misbranded or adulterated foods, drugs, devices and cosmetics. Animal feeds are subject to these same provisions, as Mr. Durbin explains in his article which starts on page 155. He concludes that those interested in livestock production "must primarily be concerned with the question of whether the food for man obtained from treated animals can possibly have any adverse effect on the human consumer. If there are any questions of safety to be resolved, they must always be resolved in favor of public health protection."

George P. Larrick, the Commissioner of Food and Drugs of the Department of Health, Education and Welfare, explains the operations of the FDA in a paper which he presented before the American Petroleum Institute. He points out the various aspects of the new hazardous substances labeling act, and its application to the petroleum industry. In his paper, Mr. Larrick invites suggestions for improvement in the regulation and administration of the statute. It appears on page 164.

The chief chemist in the Division of New Drugs of the Bureau of Medicine, Food and Drug Administration, *Earl L. Meyers,* explains the workings of his group to the American Association of Blood Banks, in an article which appears on page 169. The "full disclosure" requirement has a double purpose, according to the author. The first purpose is to make full information readily available for the maximum safety and efficacy in the use of prescription products to the medical profession and the second is to "eliminate the use of labeling for prescription products that is misleading by reason of the omission of information concerning the hazards and limitations of the product while extolling its virtues." Mr. Meyers concluded by saying that his discussion "has presented the basis for the application of the Food, Drug and Cosmetic Act to biologicals and an introduction to the major concepts contained in the revisions in labeling regulations adopted during the past year. In practice, manufacturers of biologicals will work out the labeling problems related to the revised regulations in their relationships with the Public Health Service, Division of Biologics Standards."

Bar Association Meeting.—The seventeenth annual meeting of the Section on Food, Drug and Cosmetic Law, New York State Bar Association, was held on January 24. The all-day meeting was held in the Commodore Hotel, New York City. This year for the first time a section luncheon was held as part of the meeting. The members appeared pleased with this innovation as the attendance at the luncheon approximated 100. The section was honored to have as its guests at this luncheon the Hon. J. Boyd Mullan, President of the New York State Bar Association and William Roy Vallance, Secretary-General of the Inter-American Bar Association. Jerome B. Trichter, Assistant Commissioner, Environmental Sanitation, New York City Department of Health, was prevented from attending because of illness.

The chairman of the section, Franklin M. Depew of New York City, presided at the meeting. The morning session was opened at 9:30 A. M. with an introductory statement by Mr. Depew. Two of the talks delivered that morning are reported in this month's JOURNAL. Following an interesting floor discussion at the end of the afternoon session a resolution was adopted endorsing the following recommendations to the Second Citizens Advisory Committee for the Food and Drug Administration: (1) that the Food and Drug Administration's traditional policy of adhering to the career system be maintained, (2) that the adequate funds be made available to the agency, and (3) that the agency expand its education and information program.

Following further extended floor discussion led by Irving H. Jurow, a second resolution was adopted urging that the American Law Institute reconsider the form of Section 402A of Tentative Draft No. 6, Restatement of the Law Second-Torts, and requesting that the New York State Bar Association urge the Institute to grant a hearing on the subject to give the section an opportunity to present its views and arguments.

The business meeting concluded with the election of officers and members of the Section's Executive Committee. The following were elected: Franklin M. Depew, Chairman; A. M. Gilbert, Vice Chairman; Raymond D. McMurray, Secretary; and Frank T. Dierson, James F. Hoge, William E. MacKay and Hoke S. Woodruff, Executive Committee members.

Canadian Food and Drug Directorate.—Any manufacturer wishing to sell a pesticide which may produce a residue in or upon a food for consumption in Canada is urged to submit data to this Directorate so that the residue may be evaluated in terms of consumer safety and a tolerance established by regulation under the Food and Drugs Act where necessary.

American Chemical Society Symposium.—Of interest to many readers of this JOURNAL is the forthcoming symposium of the American Chemical Society on The Role of Chemicals in Modern Food and Fibre Production to be held in Washington, March 21st and 22nd. The three half-day sessions are to be devoted to utilization, safety evaluation, and development and regulatory problems, under the respective chairmanship of Dr. A. H. Moseman, Director of the Rockefeller Foundation, Dr. C. G. King, Scientific Director of the Nutrition Foundation, and Mr. F. M. Depew, President of the Food Law Institute. Among the sixteen eminent speakers on the program are representatives of several universities, the Department of Agriculture, and the Food and Drug Administration including, among the latter, Commissioner George P. Larrick.

The first session will be held the morning of March 21. *A. H. Moseman* is scheduled to be chairman of that session. He is director of the Rockefeller Foundation and will speak on "Utility and Necessity for the Use of Chemicals in Food and Fibre Production." Other speakers at that session will be: *G. F. Stewart* of the University of California who will speak on "Maintenance and Expansion of the Nation's Food Supply"; *A. M. Boyce* of the University of California who plans to address the members on the topic "Chemicals in Agriculture and Crop Production"; Food and Drug Research Laboratory's *K. Morgareidge* has chosen "Chemicals in Preparation, Distribution and Packaging of Food" as his topic; *George W. Irving* of the United States Department of Agriculture will speak on "Chemicals in Utilization of Fibres Derived from Agriculture"; and *H. L. Haller* of the United States Department of Agriculture will be speaking on "Research Needs in Connection with the Use of Chemicals for Production of Food and Fibre."

The second session of the symposium will take place the afternoon of March 21. *C. G. King* of the Nutrition Foundation will be chairman and will speak on "Safety-Evaluation Problems Created by Chemical Residues and Additives in Food and Fibre." *Henry Smith* of the Mellon Institute will delineate the "Toxicological Aspects Associated with the Use of Chemicals in Producing Food and Fibre." The Food and Drug Administration will be represented at this session by *Henry Fischbach* who will speak on "Analytical Methods for Determining Chemical Residues and Additives in Food." *W. H. Sebrell* of Columbia University has chosen as his topic "Interpretation of Toxicological and Analytical Data in Assessing Safety of Chemical Residues and Additives in Food." The last speaker on the program for the afternoon session of March 21 is *H. C. Hodge* of the University of Rochester who will discuss "Research

Needs Associated with the Safe Use of Chemicals in Producing Food and Fibre."

The morning of March 22 is the time stated for the third session of this symposium. *Franklin M. Depew,* president of the Food Law Institute, will be the chairman of the closing session. He will speak on the "Regulatory and Development Problems Attendant to Chemical Residues and Additives in Food and Fibre." "The Scope and Responsibility of Industry in the Development and Regulation of Agricultural Chemicals" is the topic chosen by *George R. Ferguson,* president of National Agricultural Chemists Association. *K. E. Mulford* of Atlas Powder Company will speak on "Scope of Responsibility of Industry in the Development and Regulation of Additives and Adjuvants for Food and Fibre". Next on the agenda is *M. R. Clarkson* of the Agricultural Research Service of USDA speaking on "Scope and Responsibility of Government in Development and Regulation of Agricultural Chemicals." And last is *George Larrick,* Commissioner of Food and Drug Administration, who will address the members of the symposium in the "Scope and Responsibility of Government in Development and Regulation of Chemical Additives for Food."

It is also noted by the planning committee that consideration will be given to the inclusion of outstanding contributed papers that logically come under the scope of the subject of the symposium. These will be placed at the end of each session or collected for an extra session on the afternoon of March 22.

AOAC Harvey W. Wiley Award.— The sixth AOAC Harvey W. Wiley Award, sponsored by the Association of Official Agricultural Chemists, has been opened for nominations. In his announcement, Dr. Kenneth L. Milstead, president of the association, noted that the $500 award was established to recognize outstanding achievement in analytical methodology and is given annually to a scientist or scientific team who has made outstanding contributions to the development of analytical methods in the fields which are of interest to the association. These areas, food, drugs, cosmetics, feeds, fertilizers, pesticides, and general analytical chemistry, are covered in the authoritative AOAC publication, "Official Methods of Analysis," the principal laboratory manual used by regulatory scientists and researchers in agricultural sciences throughout the world. Nominees need not be members of the association.

Nominations must be submitted to the association by April 1, 1962. Complete information about the material required for support of a nomination may be obtained from the secretary, Dr. William Horwitz, Box 540, Benjamin Franklin Station, Washington 4, D. C.

Previous awards have been given to eminent researchers in pesticide residue analysis, drug methodology, fertilizer chemistry, paper chromatographic techniques and analytical chemistry of food contaminants. The 1961 award was given to Paul A. Clifford of the Food and Drug Administration in recognition of his notable contribution to the progress of analytical methodology for chemical food contaminants.

Vol. 17, No. 2 February, 1962

Food·Drug·Cosmetic Law Journal

The Federal Hazardous Substances Labeling Act

By JOHN A. ZAPP, JR.

Mr. Zapp Presented This Address on November 27 at the 1961 Joint National Conference of Food and Drug Administration and the Food Law Institute, Inc., at Washington, D. C. He Is Director, Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours and Company.

IT TOOK SOME EIGHT YEARS of Congressional hearings before a Food Additives Amendment reasonably acceptable to government, industry and consumer interests could be enacted. By contrast, the passage of the Federal Hazardous Substances Labeling Act was rapid and painless. Hearings on the proposed bill were held by a subcommittee of the Senate Committee on Interstate and Foreign Commerce on August 13, 1959 [1] and by the Subcommittee on Health and Safety of the House Committee on Interstate and Foreign Commerce on March 14, 1960.[2] By July 12, 1960, the act had been signed by the President.

It was noted in the Senate Committee Report on March 10, 1960,[3] that:

> The standards established in this bill for determining whether a substance is or is not a hazardous substance are those which are generally recognized at common law in civil liability cases relating to the sellers duty to warn users of the hazards of his products. Thus, substances to be regulated are carefully defined in the bill. These definitions are the result of meetings between industry

[1] *Hearings Before Subcommittee on Interstate and Foreign Commerce* S. 1283, U. S. Senate, 86th Cong., 1st Sess., Aug. 13, 1959.

[2] *Hearings Before a Subcommittee on Interstate and Foreign Commerce,* H. R. 5260, 86th Cong., 2d Sess., Mar. 14, 1960.

[3] *Senate Committee Report* 1158, 86th Cong., 2d Sess., Mar. 10, 1960.

groups, the Committee on Toxicology of the American Medical Association, representatives of the Department of Health Education and Welfare and State public health officials who have recognized the need for and supported legislation on this subject at the State level. . . .

The testimony of the witnesses at the hearing on August 13, 1959, and letters and statements filed by various interested persons and groups, show a remarkable unanimity of support for the principle of this legislation. There appears to be no objection to this legislation. . . .

The House Committee Report of June 10, 1960 [4] noted:

All witnesses who appeared before the subcommittee favored this legislation in principle and most of them recommended the adoption of the Senate-approved bill.

It is apparent from this record that the Federal Hazardous Substances Labeling Act was a remarkably noncontroversial piece of legislation. In no sense were industry and government adversaries with respect to either the desirability of the act or important specific features of it. The same cannot be said for the Regulations implementing the act.

I shall not presume to burden this audience with a systematic analysis of the comments which have been made on the proposed Regulations issued April 29, 1961 [5] or the final Regulations issued August 12, 1961.[6] Written comments were submitted by many individuals, companies and organizations, and are on file with the Hearing Clerk, Department of Health, Education and Welfare. Among these are the official comments of my employer, the DuPont Company. A public meeting on the proposed regulations was held in Washington on July 13 and 14. Two expert advisory panels, one composed of dermatologists and the other of physicians, pharmacologists and clinical toxicologists, on neither of which were there any representatives from industry, were convoked by the Commissioner of Food and Drugs. Their findings were filed with the Hearing Clerk, Department of Health Education and Welfare, on August 3, 1961. Many additional comments and briefs have been submitted subsequent to the promulgation of the final regulations on August 12, 1961.

So much has been said and by so many persons in this room, that I hesitate to add anything more. I am not a lawyer but I am to talk about a law. I am not here as the representative of my company's views or those of any other company, organization or committee. But

[4] *H. Rept.* 1861, 86th Cong., 2d Sess., June 14, 1960.

[5] 21 C. F. R. 191, Hazardous Substances, Proposed Definitions and Procedural and Interpretive Regulations, *Federal Register,* April 29, 1961.

[6] 21 C. F. R. 191, Hazardous Substances, Proposed Definitions and Interpretive Regulations, *Federal Register,* Aug. 12, 1961.

I am interested in the Federal Hazardous Substances Labeling Act as a citizen, as an employee of industry and as a toxicologist. I have been interested in the seeming paradox that dissatisfaction has arisen over a law which everybody wanted and even before it has become fully effective. Where such a situation arises there are always reasons, and I have tried to understand them, and I hope that my attempts may be of some interest to you.

Senate Committee Report

The Federal Hazardous Substances Labeling Act is a statute which is both specific and vague. As the Senate Committee Report [7] pointed out: "Thus, substances to be regulated under this bill are carefully defined in the bill." But the report also noted:

> Provision is made for the Secretary of Health, Education and Welfare to adopt regulations for the efficient enforcement of the Act, including the authority to declare a substance to be a hazardous substance if the Secretary finds that such substance would meet the definition of a hazardous substance in the bill, and if such action would promote the objectives of the legislation by avoiding or resolving uncertainties as to its application. The Secretary would also be authorized to establish reasonable variations, or additional or less stringent labeling requirements, if he found them necessary for the protection of the public health and safety.

Judge Learned Hand

On this point, I am reminded of some words of the late Judge Learned Hand, when he said:

> In other words, a law couched in general terms *prima facie* includes all occasions that the words cover, and therefore presupposes a choice on each occasion between some value to be attained and some sacrifice to be accepted. It assumes that its advance appraisal of each value and sacrifice in this equation will not vary too much from the latter appraisal. This assumption is not troublesome, so far as the values and sacrifices do not vary in the different settings in which they appear, but they do vary greatly, so that an occasion may arise that, although it is within the words used, imposes a choice between values and sacrifices altogether different from any that the legislators would have made if they could have foreseen the occasion.
>
> There are two ways of meeting this difficulty. A statute may rigidly declare those specific occasions to which it will apply, making it plain that it means to cover all occasions within the lexicographic scope of the words and no others. Although that will not indeed avoid all doubts, it will do so in proportion as the language is specific, as for example, when a coined vocabulary is used. It is seldom, however, that the purpose behind a statute is so limited that it is possible in advance to imagine all the occasions which the legislators would wish to include, if they had thought of them.

---

[7] Report cited at footnote 3.

The other way is to leave the proliferation of the purpose to those who are to be entrusted with effecting it; the "interpreters." This too has its defects. . . .

However, be the difficulties what they may, there can be no doubt that this second way is that adopted in countless instances in the administration of mature jural systems. Indeed, we have carried it so far in the interpretation of statutes that at times in order to effect the obvious design we have actually disregarded words or phrases whose scope admitted of no doubt, and that stood flatly in the path of the reading adopted.[8]

Judge Hand was not, of course, referring to the Federal Hazardous Substances Labeling Act, but the concepts of value to be attained and sacrifice to be accepted are there, and the device of leaving the proliferation of the purpose to those who are to be entrusted with effecting it; the "interpreters,," is there also. And it is this proliferation of the purpose beyond the words of the statute which seems to have caused the present dissatisfaction with the Regulations implementing the act.

It is plain from the legislative history of the Federal Hazardous Substances Labeling Act that industry was a full partner in its enactment. The history of federally enforced precautionary labeling of hazardous household substances begins with the Federal Caustic Poisons Act of 1927, which applied to 12 well-known hazardous substances. By the early 1930's however, industry had voluntarily executed agreements with the Surgeon General, United States Public Health Service covering the precautionary labeling of about a dozen additional substances.

By 1936, industry began unilaterally to put precautionary information on the labels of other of its products and by 1944 a Labels and Precautionary Information Committee was formed by the Manufacturing Chemists' Association. The first LAPI manual "Warning Labels" was issued as a bound pamphlet in 1946, following a mimeographed version in 1945 and has now gone through five editions. The Surgeon General, United States Public Health Service recognized the LAPI labels as a suitable substitute for those prescribed in the Surgeon General's Agreements.

It was rather generally recognized during this developmental period that precautionary information should be provided for "substances highly toxic to man." The decision as to whether a substance was highly toxic to man could often be made on the basis of historical fact. But with many new substances which were first entering com-

[8] Learned Hand, *The Bill of Rights,* Harvard University Press, Cambridge, Mass., 1958.

merce there was no basis of historical fact, and a judgment had to be made *a priori* as to whether a substance would be likely to be highly toxic to man. By 1947, definitions of "highly toxic to man" based on tests performed on laboratory animals were shaping up.

So far as I can determine this effort began with a proposal by the Du Pont Company to the Interstate Commerce Commission in December, 1946, that the definitions of Class B poisons be clarified.[9] Chief Inspector H. A. Campbell of the Bureau of Explosives referred the Du Pont proposal to the Manufacturing Chemists' Association [10] and a subcommittee of the LAPI Committee under the chairmanship of Dr. A. G. Cranch was appointed to prepare a revised definition of Class B poisons.

Federal Insecticide, Fungicide and Rodenticide Act

The passage of the Federal Insecticide, Fungicide and Rodenticide Act in June, 1947, required the Secretary of Agriculture "to determine economic poisons, and quantities of substances contained in economic poisons which are highly toxic to man." A letter dated July 22, 1947, from W. G. Reed, chief, Insecticide Division, United States Department of Agriculture,[11] contains the following paragraph:

> The subject of definition for the term "highly toxic" will have to be taken up in the regulations for the enforcement of the new Act. It is a subject to which we have given very careful consideration, including both consultation with other Governmental authorities and reference to the definition as given by the labeling and precautionary information committee of the Manufacturing Chemists' Association.

The definitions appearing in the regulations to Federal Insecticide, Fungicide and Rodenticide Act of September 26, 1947,[12] are identical with those recommended by the subcommittee of the LAPI Committee for Class B poisons.

In April of 1948, however, another subcommittee of the LAPI Committee of which I was a member, along with Dr. A. G. Cranch and Dr. J. E. Foulger, recommended some minor clarification of the 1947 proposed definitions of Class B Poisons. These are adopted by the LAPI Committee and appeared in the "Warning Labels" manual in

---

[9] H. A. Campbell, Letter to the Manufacturing Chemists' Association, Washington, D. C., Dec. 11, 1961.

[10] Letter cited at footnote 9.

[11] W. G. Reed, Letter to C. L. Smith, Agricultural Insecticide and Fungicide Association, New York, N. Y., July 22, 1947.

[12] 7 C. F. R. 162, *Regulations for the Enforcement of the Federal Insecticide, Fungicide and Rodenticide Act*, Sept. 26, 1947.

the 1949 revision. They were adopted by the Interstate Commerce Commission as definitions for Class B Poisons in 1950. They are almost identical with the definitions of "highly toxic" substances in the Federal Hazardous Substances Labeling Act.

I have cited this history simply to demonstrate that industry was actively interested in and engaged in precautionary labeling long before the Federal Hazardous Substances Labeling Act and that this activity was not an involuntary reaction to externally imposed legislation. Those who care to read the Model Hazardous Substances Labeling Act prepared by the Precautionary Labeling Committee of the Chemical Specialties Manufacturing Association in October, 1957,[13] will note the extent to which the Federal Hazardous Substances Labeling Act follows the model bill.

Yet, for reasons of which I have no knowledge, it was apparently judged best that industry should not take part in the formulation of the proliferation of the purpose of the act, to use Judge Hand's words, which is embodied in the Regulations. Rather, it began to appear that the Federal Hazardous Substances Labeling Act might have been enacted to control a reluctant and recalcitrant industry against its wishes. I can find no other reasonable explanation, for example, for the words of a Food and Drug Administration official in a speech given February 9, 1961, in which he said:

> The Bureaus of Medicine and Field Administration have assembled data which will enable us to determine which products presently on the market require warning labels under the Federal Hazardous Substances Labeling Act. This information will be used in promulgating our initial regulatory program. However, we may say that the affected industry is to a very considerable extent aware of the requirements of the Act and we may hope that a satisfactory degree of voluntary compliance will be achieved.[14]

Objections of Industry

There have been a number of objections raised by industry to the Regulations promulgated on August 12, 1961, and in the time remaining I should like to express some personal views on only three of the points at issue. These are: (1) the definitions of substances which

[13] *Model Hazardous Substances Labeling Act* for Retail Packages, Chemical Specialties Manufacturers Association, Inc., Oct. 1, 1957.

[14] M. L. Yakowitz, "The Federal Harardous Substances Labeling Act," Talk at FDA Staff Conference, Feb. 9, 1961.

are toxic, but not highly toxic; (2) the prescription of the form which precautionary labeling must take; and (3) the prescription of the methods by which certain toxicity tests are to be carried out.

The first issue relates to how one should define substances which are toxic, but not highly toxic as defined in the act. The House Committee report [15] laid down this guide line:

> It is the Committee's intent that animal experimentation data may, in accordance with appropriate scientific methods, be used as a basis for determining whether a substance is capable of producing injury or illness to man.

This, I believe, should be related to another statement by the House Committee: [16]

> The term "substantial" in the expression "substantial personal injury or substantial illness" should be read in the light of the purposes of the bill. On the one hand, it is not intended to impose the impracticable and self-defeating requirement of cautionary labeling against wholly insignificant or negligible illness or injury, such as the very temporary indisposition that a child might suffer from eating a piece of the standard type of toilet soap. The Committee recognizes that virtually every substance used in or about the household is capable of causing some degree of illness or injury if accidentally or intentionally misused. If labeling were required to caution against the risk of even the most trifling indisposition, there would hardly be any substance going into the household which would not have to bear cautionary labeling, so that consumers would tend more and more to disregard label warnings, thus inviting indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness. On the other hand, the term "substantial" is not intended to limit the requirement of cautionary labeling to situations in which the injury or illness to be guarded against would be severe or serious.

The intent of the legislators seems perfectly clear. They wanted cautionary labeling applied to those substances which might cause a substantial injury or illness. They defined "substantial" as something greater than "insignificant," "negligible," or "temporary indisposition" and as something less than "severe" or "serious." They were concerned with the danger of overlabeling so that consumers would tend more and more to disregard label warnings, thus inviting indifference to cautionary statements. They directed that animal experimentation data may, in accordance with appropriate scientific methods, be used as a basis for determining whether a substance is capable of producing injury or illness to man. It was left to the "interpreters" to proliferate this purpose into a set of specific directions in the Regulations to the act. And it created a kind of legal-scientific dilemma which may become increasingly familiar.

---

[15] Report cited at footnote 4.

[16] Report cited at footnote 4.

Let me state at the outset that no one, to my knowledge, has any quarrel with the legislative purpose relating to the definition of toxic substances. But how is this purpose to be translated into a rule of conduct?

Scientific Issues

Let us first consider the scientific issues. There are undoubtedly substances which are less toxic than "highly toxic" as defined in the Act, but which deserve to bear warning labels because they are hazardous substances as a matter of historical fact; for example, kerosene. And there is a gray area involving substances whose hazard is largely presumptive, and where there is no background of historical fact to fall back upon for guidance. One can make an estimate of whether substances are likely to be hazardous for man because of toxicity by studying their toxicity on experimental animals. Then one can make a more or less intelligent, but not infallible, extrapolation of the animal results to man and by coupling this with an estimate of the likelihood of human exposure to the substance, arrive at an estimate of the probability that substantial injury might occur. If the best estimate of hazard would lead a reasonable man to the conclusion that substantial injury might occur if such a substance were a household substance, then I believe that both government and industry would agree that cautionary labeling would be indicated. The only question at issue is, therefore, one of procedure for arriving at the best estimate of hazard.

Here, however, science and the law supply different answers. Science is used to gray areas where knowledge is imperfect and where the best estimates of today may need to be revised when more complete information becomes available. Lawyers, on the other hand, prefer to avoid gray areas. As Justice Holmes remarked in 1881:

> In other words, the standards of the law are external standards, and however much it may take moral considerations into account, it does so only for the purpose of drawing a line between such bodily motions and rests as it permits, and such as it does not. What the law really forbids, and the only thing it forbids, is to act on the wrong side of the line, be that act blameworthy or otherwise.[17]

Acting in accordance with this principle, the law would, if possible, draw a line, and the Regulations to the Federal Hazardous Substances

---

[17] O. W. Holmes, *The Common Law*, Little, Brown and Co., Boston, Mass.

Labeling Act have drawn a line or more accurately two lines with respect to oral and inhalation toxicity which establish check points of toxicity for experimental animals. The first line is drawn so as to include all substances whose toxicity is equal to or greater than one-tenth the toxicity of the least toxic "highly toxic" substances as determined by tests on experimental animals. The second line, for oral and inhalation toxicity is drawn to include all substances whose toxicity is equal to or greater than one one-hundredth the toxicity of the least toxic "highly toxic" substances as determined by tests on experimental animals. Substances falling between the first and second lines would have to bear cautionary labeling unless industry could argue effectively that they were not, in fact, hazardous substances within the meaning of the act.

One effect of the lines is to throw a tremendous burden of testing on industry, the cost of which will ultimately be borne by the consumer. They also open up, however, the possibility of that overlabeling which in the words of the House Committee would tend to lead consumers "more and more to disregard label warnings, thus inviting indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness."

The dilemma here, as I see it, is that it is scientifically impossible to draw a line which will separate the sheep from the goats with any degree of precision. And yet this is what the regulations have sought to do. The dilemma should be resolvable but to accomplish this resolution will require the best efforts and cooperation of both the scientists and the lawyers and some give and take on the part of each. It requires an equation between values to be attained and sacrifices to be accepted.

Form of Warning Labels

The second item at issue, namely the prescription of the form that warning labels must take, does not, so far as I can see, involve any scientific issues. Government apparently feels that even the best labeling practice of industry to date is inadequate for the protection of the public health and safety, and hence must be changed. They suggest an alternative form of as yet untried effectiveness. And there is no body of either historical or scientific fact that would lead to an objective resolution of the issue. It is a fact, however, that the mandatory relabeling of substances already packaged would cost industry, and ultimately consumers, millions of dollars and many man-hours of work which would otherwise be devoted to other things.

While the main issue is whether a new form of labeling is good and the old forms bad, the immediate subsidiary issue may be this: Does the protection of the public health and safety require that a change in virtually all existing warning labels be made by February 1, 1962? If the answer is affirmative, what is the equation between the values to be attained and the sacrifices to be accepted?

Finally there is the issue of the prescription of the test methods for evaluating the toxicity of substances through animal experimentation data in accordance with appropriate scientific methods. This issue, like the first, involves a legal-scientific dilemma.

If one is to make a decision on the basis of evidence derived from experimentation on animals, how is that evidence to be obtained? What are appropriate scientific methods? The simplest way to provide *legal* evidence that a substance is or is not a hazardous substance would be to set up a technical rule saying, in effect: "Do the test this way and come up with a number. The number obtained will be less than, or equal to, or greater than a given number, A. If it is equal to or greater than A, the substance must bear cautionary labeling."

Such a technical rule has the virtue of simplicity, and the Regulations have adopted this approach for determining skin absorption toxicity, skin irritation and eye irritation. No rule is given, however, for determining oral or inhalation toxicity or skin sensitization potential although one might presume that rules covering these will be added at some time in the future. What is the scientific issue?

I think it is fair to state quite simply that there is no agreement among scientists that there is any one "appropriate" scientific method of obtaining animal experimentation data. This does not imply that scientists are hopelessly at odds over questions of what is sound and unsound procedure, but rather that the many questions arising out of the use of experimental animals for estimating *human* responses are not yet fully resolved. Animals tested with a given substance in one laboratory sometimes will respond somewhat differently from those tested in another laboratory for reasons involving biological variations of one sort or another. The cause of the difference may be determinable, for example, differences in strain, or in the diet of the animals, but it is not so easy to say which of the different responses is the "correct" one. And even if methods of animal experimentation could be standardized to the point where everybody got the same results, the question arises as to whether these results would most correctly estimate human responses.

This audience will recall, I am sure, the pleas made at the meeting of this group following passage of the Food Additives Amendment that methods for testing the safety of food additives should not be frozen. And they were not. The Regulations to the Food Additives Amendment of 1958 say (121.6(a)) that the Commissioner will "be guided by the principles and procedures for establishing the safety of food additives stated in current publications of the National Academy of Sciences—National Research Council" but add: "A petition will not be denied, however, by reason of the petitioner's having followed procedures other than those outlined in the publications of the National Academy of Sciences—National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedure".[18]

This kind of open-endedness is, in my opinion, scientifically sound and I had hoped to see some such wording in the Regulations to the Federal Hazardous Substances Labeling Act. Perhaps its absence reflects a legal sort of dissatisfaction with a definition which is not a good technical rule. I can imagine a lawyer saying, "If I take you to court I want to be able to base my case on the results of a particular official test, and I don't want to have to argue the merits of *your* test." My answer is that the science of toxicology is not ready at this time to be confined by such a technical rule, and that it is a disservice to try to so confine it.

I would not attempt to dissuade the scientists of the Food and Drug Administration from using the methods they are accustomed to use. But I do not feel that my laboratory could make any better estimates if we blindly copied the Food and Drug Administration methods than we make with our present methods. And I believe that my colleagues in other laboratories feel the same about their methods. Yet we are all seeking the truth by what we believe to be the best available techniques. Out of the diversity of our methods there may come real progress toward the attainment of our common goal, better estimates of human responses without using human subjects.

This third issue, the prescription of test methods, involves as I have said, a legal-scientific dilemma. But above all, like the other two, it also involves the equation of value to be attained and sacrifice to be accepted.

---

[18] 21 C. F. R. 121, Subpart A—Definitions and Procedural and Interpretive Regulations, *Federal Register,* Mar. 28, 1959.

In the solution of this question, it is my belief that government would benefit from the best thinking of industry. I regret therefore, that industry has apparently been relegated from the role of the co-operator to the role of the regulated. If industry and government could attack their mutual problems and dilemmas as associates, as they have in the past with similar legislation, rather than as adversaries, it is my belief that both will benefit and that an optimum balance can be reached between those values that should be attained and those sacrifices that must be accepted by both government and industry in the proliferation of the purposes of the Federal Hazardous Substances Labeling Act. **[The End]**

COUNTERFEIT COSMETICS SEIZED

United States marshals have seized over 4,800 bottles of hair dressing in the first of five actions against a cosmetic counterfeiting operation. The Food and Drug Administration said the man behind the operation is now awaiting sentencing for counterfeiting United States currency.

The seizure was made February 8, in second floor rooms over a Clinton, Maryland auto repair shop, FDA said. The agency also said approximately 9,000 bottles of hair dressing bearing counterfeit labels are being held by four dealers in New York and New Jersey pending federal seizure.

The product—a counterfeit of Vitalis produced by the Bristol Myers Company of New York City—was made for Francis Anthony Agresti of Silver Springs, Maryland, who recently pleaded guilty to a currency counterfeiting charge in Federal District Court at Baltimore.

The 4,800 barber-shop sized bottles, which were trucked to Clinton from a cosmetic manufacturer in Philadelphia, had been labeled as "Buno Hair Dressing." Most of these labels had been removed from the bottles and the remainder were being soaked off by an employee.

FDA said analysis showed the counterfeit product contains coal tar colors not present in the genuine product. Differences were found in the containers and labels also.

Seizure papers charged that the product seized at Clinton, as well as the other 9,000 bottles, was shipped by Emil Laboratories in Philadelphia to Agresti, doing business as Robin Sales Company, in New York City. Agresti had made arrangements with several manufacturers for production of bottles, bottle caps, shipping cartons and fake labels. None of these labels were found with the product at Clinton.

FDA said the counterfeit product has been sold to wholesalers and barber supply companies as distress merchandise at cut-rate prices. Court papers charge it is misbranded under the Federal Food, Drug and Cosmetic Act.

FDA Commissioner George P. Larrick commented: "As in cases of drug counterfeiting, the counterfeiting of cosmetics can lead to health dangers as well as economic fraud. Serious risks are present when products are not produced under normal conditions and safeguards. Impure, untested or otherwise abnormal ingredients may be used. We do not intend to allow this type of violation to spread."

Fallout and Our Food Supply

By S. ALLAN LOUGH

Mr. Lough Is Assistant Director for Radiological Physics, Division of Biology and Medicine, Atomic Energy Commission. This Paper Was Delivered at the 1961 Joint National Conference of Food and Drug Administration and the Food Law Institute, Inc. on November 28, at Washington, D. C.

SINCE THE FIRST NUCLEAR WEAPONS were exploded about 16 years ago we have had an opportunity to study the ways in which the fission product debris is distributed in the atmosphere, on the earth's surface and in our food supply. Fortunately, it has been possible to take advantage of this opportunity during the years, and, while there remain many unanswered questions, the information available at present provides enough knowledge to assure us of a rather reliable concept of the situation. The picture we have refers only to the behavior of fission product debris resulting from testing of weapons, but qualitatively the conditions should not be grossly different in the event of a nuclear war.

If a nuclear weapon is exploded at or near the surface of the earth, the radioactive products are introduced into the troposphere in every case, and also into the stratosphere if the weapon is of large yield. It would appear that in the use of such weapons the fission products, present in either the troposphere or stratosphere, will settle sooner or later to the earth's surface. The rate of deposition depends upon numerous conditions. A surface burst will produce large particles of soil to which fission products will be attached and these will settle rapidly. Rainfall sweeps the debris from the troposphere. The meteorological relationships between the stratosphere and the troposphere determine the rate of movement from higher to lower layers of the atmosphere.

Most of the fission products exhibit a short half-life, hence disappear rapidly because of radioactive decay. These radioisotopes of

short half-life are of concern primarily in the area immediately surrounding the explosion center and in the early period after burst.

Deposited materials emit beta particles and gamma rays and deliver an external radiation dose. But contaminated foods, when ingested, deliver an internal radiation dose. How do fission products reach our food?

During periods of active fallout these radioactive materials are deposited on the leaves of plants and on the ground. From each location they can be absorbed by plants, that is, by foliar absorption and by root uptake. Both modes of entry into plants are important, but not equally so for all fission products. Cesium 137 is rather firmly fixed by the soil and hence is not taken up readily through the roots. Cesium would appear in or on plant tissues in significant quantities, therefore, only during periods of active fallout. A new crop grown after deposition is all but complete would be relatively free of cesium 137. Strontium 90, in contrast, is not fixed so firmly by the soil and, hence, is more readily absorbed through the roots. As a consequence it will appear in plants not only during periods of active fallout, but also to a very real extent over extended periods of time. Fission products can be ingested by animals and humans whether the contaminating substances are in, or only on, plant tissue. And humans can ingest those which are metabolized by eating animal products such as meat or milk. Of those which exhibit a short half-life, iodine 131 (half-life, eight days) is of principal concern since it enters milk readily. Diversion of contaminated milk, or storage of dehydrated milk to allow the iodine to decay, would be two methods of handling this situation.

The two long-lived fission products of chief dietary concern are cesium 137 and strontium 90, both of which exhibit a half-life of 28 years.

Such cesium 137 as may be in or on plants is readily absorbed from the gut and is distributed mainly to the blood and soft tissues of the animal. Meat and milk, therefore, as well as plants, are the chief sources of cesium 137 in the diet of humans. The biological half-life of cesium 137, the time required for excretory removal of one-half of the amount which may be present in the body, is about 100 days. If ingestion stops, or is markedly reduced, the organism is measureably capable of reducing the radiation dose from cesium 137 because of this relatively short biological half-life. Since this radioisotope emits beta particles, which travel only a few centimeters in tissue, and also

gamma rays, which penetrate throughout the body, cesium 137 delivers what is called a whole body dose and hence will irradiate the gonads rather effectively.

Because of its ready absorption from the soil by plant roots, strontium 90 will be a more persistent contaminant in foods, even long after the process of fission product deposition has eased. Strontium is metabolized much as is calcium, hence most of the strontium 90 goes to bone. Since it emits only beta particles the radiation dose is limited to the tissue immediately surrounding the disintegrating atom of the isotope. It has been observed that in the human lactating female only about 1.3 per cent of ingested strontium 90 appears in the milk. Furthermore both animals and humans discriminate against strontium in favor of calcium. The ratio of strontium to calcium in the bone of adults is only about 0.25 of the ratio found in the diet. The ratio of strontium to calcium in milk is about 0.10 that in the diet. In this instance a metabolic defense exists to reduce the ultilization and hence bone deposition of strontium 90. Observations in human infants have shown, however, that at very early ages there is much less discrimination against strontium. Indeed the ratio of strontium to calcium in the bones of very young children who died in early 1961 is about four times as great as in adults who died in the same period.

Remedial Measures

The problem of strontium 90 contamination of foods has been attacked with the hope of finding remedial measures by which the amount of radiostrontium in foods could be markedly reduced. As a long-term program this kind of effort should be more intensively pursued. So far as I know there is only a limited amount of research in progress along this line.

Some investigations have been made in an attempt to remove strontium 90 from milk by passage over ion exchange resins. Sometimes flavor changes have been produced; in any event the calcium is removed along with the strontium 90 and calcium must be returned to the milk. Even if developed satisfactorily from a technical standpoint, the procedure appears to be so costly as to be uneconomic.

Another approach has been to treat milk with precipitated tricalcium phosphate to allow strontium 90 atoms to displace calcium from the additive which would be removed finally by passing the mixture through a filter press. Two attractive features of this idea are

that no calcium is removed from the milk and large volumes could be handled at relatively low cost. Probably there are some practical problems, but so far as I know this procedure has not been given the additional intensive study it seems to merit.

A search might be made for chelating agents capable of complexing strontium 90 and cesium 137 which would be effective at levels of administration low enough to be tolerated by the human and still be effective in preventing retention and utilization. For at least one metal which is an essential dietary component chelating agents have been found which are so effective that deficiencies of this metal have been produced in animals which received diets containing an ample supply of the metal. An effective and tolerable chelating agent for strontium or cesium might be difficult to find, but it seems that an effort should be made along this line.

Plant breeding offers hope in this connection. Mutants and varieties should be sought which would do either of two things. An effort should be made to develop crop varieties which reject strontium, or cesium, or both. Such varieties could be grown on contaminated soil and used directly as safe food. Of less direct, but still of real benefit would be varieties of plants which would take up strontium and cesium avidly. Such crops could be harvested and destroyed. This would clean up tracts of land and make them suitable for planting of food crops.

Thus far these remarks have been applicable to conditions which would prevail after a nuclear war.

Has the weapon testing program resulted in sufficient fission product deposition to justify great concern? Rather than burden you with a mass of data which would require a long discussion for interpretation, let me summarize the story by relating the radiation arising from deposited fission products to that which we receive from cosmic rays and naturally occurring radioactive substances. But first, let us consider a few numbers.

Strontium 90 reached its highest levels in United States milk during the period from May to June, 1959. From July, 1957 to February, 1959 values ranged from 5 to 10 micromicrocuries per liter. Between March and July, 1959 the levels were from 10 to 17 micromicrocuries per liter, and between August, 1959 and July, 1961 the strontium 90 concentration fell to about 6 to 8 micromicrocuries per liter. These numbers should be contrasted with the recommendation

of the International Commission on Radiological Protection. This group of experts has suggested that the general population could consume milk containing as much as 67 micromicrocuries per liter without undue concern. The International Commission has opined also that human bone could withstand successfully the radiation dose which would be delivered by a concentration of 67 micromicrocuries per gram of calcium. It is heartening to note that bones of children who died in 1960 have been found to contain only about 4 micromicrocuries of strontium 90 per gram of calcium, while the bones of adults contained approximately 1 micromicrocuries per gram of calcium.

The cesium 137 content of milk, and of meat, and of people has been found to rise and fall with the rate of fission product deposition. This observation is related to the fact that cesium is absorbed by plants from soil much less readily than is strontium 90. As a consequence the deposition of cesium 137 will not result in a long continuing contamination of the diet unless it is produced rather constantly and introduced regularly into the atmosphere. It has been estimated,[1] furthermore, that if equal amounts of cesium 137 and strontium 90 were ingested, the highest average absorbed dose which any tissue will receive from strontium 90 would be more than 100 times the corresponding values for cesium 137. The British report concludes: "On this basis, it seems clear that the radiological significance of caesium 137 in the diet is considerably less than that of strontium 90 even though there is evidence that as much caesium 137 may be contributed by meat in the adult diet as by milk."

Radiation from External Sources

We are subjected constantly to sources of radiation which surround us. Cosmic radiation and radiation from naturally occurring radioactive substances such as radium, uranium, thorium, and potassium 40 comprise this "background radiation." A comparison of the 30-year radiation dose from background at sea level with that from all fission products deposited from weapons tests up to this time reveals that in continental United States the background dose is about 20 times that from fission products. The Federal Radiation Council Radiation Protection Guide for normal peacetime uses of radiation

[1] Agricultural Research Council Radiobiological Laboratory. Report for 1960. ARCRL 5. "Surveys of Radioactivity in Human Diet and Experimental Studies."

allows an exposure to the general population approximately 30 times the external dose due to fission products deposited in past tests.

Radiation from Internal Sources

The population group exposed to the highest concentration of strontium 90 in bone is made up of persons born within two years after the test series which have been completed. The 70-year dose to bone from background in this group, conservatively estimated, will be about four times that delivered by fission products deposited in the skeleton. The dose from fission products will be only about 1/14 as great as the Federal Radiation Council Radiation Protection Guide for the general population's bearable risk due to normal peacetime uses of radiation.

When one recalls that the external background dose at Denver is nearly twice that at sea level, it would seem evident that one would not be justified in concluding that the amount of fission products deposited to date has seriously contaminated our food supply. Our concern about fission product deposition is justified, however, for it has led us to study the problem thoroughly and has permitted us to understand rather well the extent of the influence which this new component in our environment might exert under the more severe conditions which would be associated with a large-scale release of these radioactive materials. **[The End]**

DRUG ANTITRUST BILL NOW BEING REWRITTEN

At the close of hearings on S. 1552, the "drug antitrust" bill, Senator Kefauver announced that the Antitrust Subcommittee is now in the process of amending the bill to reflect suggestions made during the hearings on the bill. These concluded on February 6, at the end of testimony on ethical drug advertising by witnesses specializing in such advertising.

The bill in brief . . . As introduced, the bill would have made a number of changes in the patent and other provisions affecting drugs. Patents would be made effective with the filing of a new drug application (if required) or application for a patent. Compulsory licensing could have been required after three years, with an 8 per cent limit on royalties. Modification patents would be granted only upon a showing of "significantly greater" therapeutic effects. Applicants for new drug licenses would be required to prove efficacy, as well as safety. Certification would be required for all antibiotics, instead of just those named in Section 502(1) of the Federal Food, Drug, and Cosmetic Act. Labeling and advertising would have to be more detailed, and generic names could be required. Prescription drug manufacturers would be licensed. And agreements to eliminate patent interference could violate the antitrust laws. FOOD, DRUG, COSMETIC LAW REPORTS.

Consumer Education in the Food and Drug Field

By EDITH H. SHERRARD

Mrs. Sherrard, a Staff Associate for Social and Economic Issues in the American Association of University Women Gave This Address at the 1961 Joint National Conference of Food and Drug Administration and the Food Law Institute, Inc. on November 28, at Washington, D. C.

MY TOPIC is "Consumer Education in the Food and Drug Field;" but before I go into that I want to say a few words about psychological motivation in consumer education.

Now by psychological motivation I am not referring to the packaging controversy. I don't mean the bigger bang the consumer gets out of buying the jumbo box as distinct from the large one.

No, by motivation, I mean the simple ancient question, Why do consumers want to be "educated" about their buying world? Why should "this" particular audience be bothered reading "this particular printed page?"

The fact of the matter is that one must grant different motives to different people.

Do "you" wish to become an expert on, say, the selection, use or care of synthetic fabrics? Then our American Association of University Women consumer study program is not for you, even if you were eligible, because neither "training experts" nor home decoration is its objective.

Do "you" want to become a fulltime consumer balancing your nickels and dimes at the margin before you buy anything? We can't help you there either; for our consumer program is designed for people who exercise a variety of community responsibilities; and while many of them are ardent consumers, "balancing at the margin" is something most of them reserve for air conditioners or hi-fi's. And

other organizations are specialized to provide that kind of service—not American Association of University Women.

Do you like to think that for every problem there is a solution—and usually a simple solution at that? I doubt that you do; but in any event, there too we must beg off. One branch of the American Association of University Women consumer program—perhaps the oldest—is concerned with the development of consumer standards. And we have learned from our 25 years of work with the American Standards Association that the problems of satisfying the needs of manufacturer, retailer and consumer in the development of a standard are complicated, even in a situation where one may count upon good will and good intention from all parties.

The motive behind our American Association of University Women consumer program—not to be coy about it—is simply the desire of educated women to seek and attain some new threshold of understanding in the face of the revolution that has occurred in the buyers' market since World War II.

You will be interested to know that discussion papers from your 1959 FDA-FLI Conference provided us with substance for the first section of American Association of University Women's Consumer Kit. We said in our introductory note on purpose:

> A great increase in the variety of goods available to the consumer coincides with a degree of economic prosperity that makes it possible for her to buy them.
>
> "Increase in variety" requires the producer and consumer to build . . . a new body of knowledge about this technological advance. The consumer must acquire a "know-how" [about her consumer world] that matches her grandmother's learning about electrical applicances and her great grandmother's experience with "canned" goods. . . .
>
> Having regard to the public's role, we might also take this as a guide to AAUW study and action. It behooves consumers to find out about the changes going on in their buying world, and so to minimize *for themselves* the hazards and dangers inherent in large scale innovation.

In saying this, we do not relieve industry of responsibility for achieving a large part of the new threshold of understanding. We do not diminish the role of government. We only say that in addition to everything else, the consumer herself has to find out about the changes going on in her buying world—not as an expert but as one who lives in that world—and that is the orientation for our consumer program.

Now having explained what we are after, I would like to mention two consumer projects we have underway.

The first, in time, concerns the American Standards Association which I mentioned a moment ago. And though this project may seem a little "special" I mention it briefly because it exemplifies the approach we are trying to develop for ourselves in various fields of consumer concern.

American Association of University Women members in the New York City area represent the Association on the sectional committees of American Standards Association, where manufacturer, retailer and consumer formulate standards for consumer goods. Recently we launched a group in New York, drawing on our local branches in New York state, Connecticut, New Jersey and Pennsylvania—a group which is to meet regularly and afford discussion of opinion for the American Association of University Women-American Standards Association representatives. These American Association of University Women members will read about standards. They will "shop" in advance of each meeting for a common list of items to find out if they can easily obtain the factual information they want; and at the meetings they will compare notes on their findings. Finally, they will discuss with their colleagues on American Standards Association committees some of the redhot controversial issues, such as "what do you mean by a coffee-cup" when the word is used to define, say, a coffeemaker with a ten-cup capacity.

By participation we hope the project will help us to become aware of complexity so that we may make a useful contribution at American Standards Association meetings without giving up the desire to see complexity resolved.

Now that was our reason for forming the group—and my reason for telling you this story. But there is another interesting circumstance to report about it: Though our New York group is only a month or two old, a second group has formed in Washington to listen to tape-recordings of the first, to "shop" for similar items, and to join in the same debate of issues. Furthermore, Philadelphia American Association of University Women has expressed an interest in joining in; and a Pittsburgh American Association of University Women member is pondering the launching of another group there. Half a dozen individual American Association of University Women members have asked if they might join "in writing"—since they cannot travel to the meetings. What is even more significant, these groups and potential groups have all emerged spontaneously. And if any one persists in the view that consumers prefer to be ignorant, or like

to be fooled, our recent experience in talking to American Association of University Women members, and in watching the development of this American Association of University Women program certainly are evidence to the contrary.

My second project, on food and drug work, is of course of greater interest to you. This was launched late last summer, as an outgrowth of the annual meeting of the Association of Food and Drug Officials of the United States which I attended in June and for which I collected some information on consumer interests in American Association of University Women.

The proposition on that occasion was to find how much more information American Association of University Women members would like to have about foods, drugs and cosmetics and about food and drug work.

We employed two different questionnaires—the second we assumed an improvement over the first—asking the American Association of University Women consumer what she had "on her mind." By and large, what she had on her mind was safety, variously expressed, but I'm not going to list the tally for each item under our several headings. Much more interesting and revealing than the figures were the comments we invited the respondents to note on the back of the questionnaire.

Of the total American Association of University Women members filling in both questionnaires, 116 made comments. Many expressed opinions on several subjects, and of these we identified a total of 122 comments as bearing on food and drug programs. These in turn we grouped in categories. And of these, three categories predominate. They are: protection against misleading information, the need for more adequate labeling and, not surprisingly, safety.

Under the heading, "protection against misleading information," American Association of University Women members wanted to know that information on the label was absolutely true and safe. They did not like obscure, pseudoscientific terms. And they wanted to have some assurances that the product would do what the producer said it would.

Under the heading "the need for more adequate labeling" came requests for more frequent use of labeling, more adequate information on labels, and more conspicuous labeling. Some people wanted more information as the basis for comparative shopping. Others wanted more information about weights and measures. Under

directions for using specific products, some referred to cooking instructions, and others to guidance as to which cleanser could be used on which substance.

Then as to "safety," the majority said simply: "Put your emphasis on safety." I would judge that the average consumer's concept of safety, as of sanitation or sanitary conditions, reflects not only an absolute—that is, everything should be perfectly safe—but also a complete lack of knowledge of what degree of safety she now has, how much or how little.

Next comes a category, "more information about ingredients"—that is to say, the circumstances in which ingredients are harmful, or useful, as well as the need to know more, to undertake research about the effect of ingredients. American Association of University Women members referred to the effect of ingredients in causing allergies, to the possibly harmful effects of ingredients in drugs.

Next, came "confusion in relation to size of container," and annoyance over prices increased by fancy packaging and other forms of "waste." The only comment one need make here is that annoyance over confusion about weights and prices is just as strong as the feeling of being misled or gypped by this confusion. Some of our respondents are quite willing to believe that they are not being gypped, but they still feel a better arrangement ought to be possible.

These were the significant remarks. Others expressed an interest in FDA activities, and the jurisdictions of federal, state and local authorities in food and drug work.

Beyond our specific findings, as I said in June, we were struck by the vagueness of knowledge about food and drug activities which this very "literate" population possesses. American Association of University Women members are "educated" people, and they are not at present being reached in this branch of consumer affairs. If I may cite a single example, some respondents seemed surprised to learn from the implications of our questionnaire that FDA officials do not now officially approve all food items that appear on the shelves—in the literal sense of "grant their approval" to such items.

Having found out what more 250 American Association of University Women members believe they would like to know, as consumers, about food and drug work, we considered it only fair to speculate as to how such information might be made available.

We looked into every technique of community education we knew about: displays of informative literature in libraries, spot news on

radio, exhibits at state fairs, all day workshops, "fillers" in newspapers. We considered which community organizations might be willing to cooperate in putting which techniques into effect. We thought, for example, that someone from the League of Women Voters would be best able to trace out and explain the network of jurisdiction of authority and enforcement in a particular community—what comes under health, under sanitation and so forth. We thought that a member of the American Home Economics Association might provide the background information for which need seemed to develop. We thought an American Association of University Women member might spend a day with a food and drug official and join in his inspection tour in order to find out what goes on.

This is where we were at the time of the Association of Food and Drug Officials of the United States meeting in June—making suggestions for a public education program about food and drug work, but making them in the abstract, so to speak. Then, late in the summer, the chairman of our national Social and Economic Issues Committee, who is the member of our national board concerned with association programs in this field, decided that we might try out a limited project of public education along these lines ourselves—and specifically we might start with those American Association of University Women branches in cities where FDA has testing stations. As noted we launched this project late in the summer, and we cannot say now in November that it is any more than afloat. It will be a year before we have measurable progress to report. Our Atlanta, Los Angeles, Philadelphia and Kansas City (Kansas) branches have signaled that they want to give the project a try. I have talked with the officers of the Kansas City branch, and on Friday of this week I am going to confer with Philadelphia American Association of University Women about their plans too.

So I am only now in the process of seeing where this project will take us. Local American Association of University Women groups will have to decide, from their own investigation of food and drug work, what information they think it most useful to publicize, who they believe would benefit most from food and drug education, and how that "education" is to be accomplished. In setting up this program we have emphasized to them that we are talking of food and drug work as it now exists, and not as some ideal of what it ought to be, that we are talking about the whole complex of local regulation, as well as state and federal law, and that we include any activities, private as well as public, to instruct and protect consumers in this field.

If you wish a glimpse into the planning sessions of a women's organization, I would guess that in Philadelphia on Friday we will number 10 or 12. There will be leaders from our local branches, two from the state of Pennsylvania and the national representative from the area as well.

We will probably begin by reading over the findings I reported to Association of Food and Drug Officials of the United States. Some suggestions based on community education in Philadelphia will be added. We may try to outline a study program for half a dozen people for half a dozen sessions designed to acquaint them with food and drug activities. We have a number of members of the American Home Economics Association in our own Philadelphia membership and they will probably take over direction here. Others will examine our two questionnaires and wonder how you might adjust them for other community organizations than American Association of University Women. I will take along as many of the talks made here as I can get away with—and though it may come to you as a surprise, you too may be part of an American Association of University Women study group.

That is as far as I can go today on the project of Friday next, but if I cannot predict or report on our project, in its later stages, it seems only fair to the audience that I speculate about it. What do we in American Association of University Women envision as happening? What shape do we expect this program to take?

If you ask that as a purely practical question we might consider the New York group working with American Standards Association as a key to this second picture. As I said, each branch will devote a certain amount of time to finding out just what food and drug work is all about—and to interviewing business men and officials of the appropriate agencies. Specific local problems will come in for special attention, if past experience serves as a guide. Perhaps a single-sheet "giveaway" of information might be developed fairly early in the program. We seem to consider it our mission to dispel error as soon as we have uncovered it, and I can visualize something that says:

Don't leave dangerous or poisonous substances where children can find them, and don't store them in soft drink bottles.

Avoid the thaw-freeze-thaw sequence.

Put your left-overs in the refrigerator within an hour, and keep them refrigerated until re-serving or re-heating.

And having devised the giveaway, I would expect some time to be devoted to deciding how one would circulate this literature, how one would reach a young mother, say, in a public housing project.

These programs as they develop will bear the stamp of our value judgments. But I would also expect a certain amount of time to be devoted to finding out what other consumers have on their minds—do older people rate health or longer life as number one among their concerns, for example, and what does this mean in terms of food and drug work?

I would expect some time to be devoted to preparing information for all kinds of different kinds of audiences. (For we believe in psychological movitation all right!)

In sum I would expect to find some of these elements I have mentioned common to all of our programs, but I would be surprised if any two programs were the same.

Essentially for us in American Association of University Women this is a project in public education rather than a project in consumer education. We are interested in knowledge about the consumer's changing world, not in promoting food and drug work—nor in confining it for that matter. Our objective, at this point, is how to make use of information, not how to create it or add to it—although we will almost certainly "spell it out!"

But if your question (about our expectations for this project) was not purely practical, if you were asking why we thought this venture worthwhile, I could only say that the Association itself exists on the premise that people are better off for understanding their world, and particularly is this true when their world is in process of change. Next, we believe that this suggests a motive to industry and to government to join in what might be a mutually advantagous venture—namely to dispel the kind of confusion and misinformation that some part of the public seems to rejoice in at the moment of crisis. If you don't want "scare" headlines, or ill-considered demands for legislation, then you too must have some stake in the kind of program we are trying to conduct.

As I said at the beginning, different people have different motives. The motives of the buyer are not those of the seller—nor is there any reason why they should be. There will be times, I expect, when your interest in the program of FDA and that of an American Association of University Women branch will be different but unless you are dedicated to the proposition that the market place is divided into

factions, each of what benefits only at the expense of the other, then you too can accept our premise that people are better off for understanding their world. Certainly the popular concept of government in the United States rests on the assumption that ordinary people will try to understand the law and participate in its effectiveness.

We concede that some consumers like to be fooled some of the time—or why else would so many of us be reading those cosmetic ads still? But we dislike the exploitation of confusion for its own sake. And if any of our American Association of University Women branches, posed on the edge of this new venture, come to you for help, whether "you" represent industry or government, we hope you will join us and respond in the same vein. [The End]

REDUCING-PILL PLAN DECEPTIVE

Claims of appetite control and weight reduction for Regimen Tablets, nationally advertised as effective without drastic diet changes, are false and misleading, the Food and Drug Administration charged in a misbranding case filed February 13 at Denver, Colorado.

FDA in a seizure action against the product challenged the following claims for Regimen Tablets:

They will cause weight loss up to six and one-half pounds in seven days and 19 pounds in six weeks without planned dieting; they will satisfy hunger, control, inhibit and shrink one's appetite causing pounds and inches to melt away; they represent a combination of reducing drugs so amazing that one can lose weight without planned dieting while eating with "gusto" one's favorite foods, and they have been proved amazingly effective in clinical tests on overweight people.

Also attacked were claims that people have lost as much as three pounds in the first three days of taking the tablets; that weight loss will be permanent; that one must lose up to six pounds in just days with the tablets and many more pounds thereafter; that excessive weight makes cirrhosis of the liver more possible than in slender folks and that it has been shown fat people are more susceptible to cancer than others.

FDA said these claims appeared in promotional materials and in Denver newspaper advertisements sponsored by Drug Research Corporation of New York City. One of these advertisements was displayed with the Regimen Tablets at the point of sale, the agency said.

United States Marshals seized a quantity of the "three-way drug combination" tablets with display cartons and circulars at a Walgreen Drug Store and the Walgreen warehouse in Denver. The tablets, distributed by Drug Research Corporation, come in green, yellow and pink colors, each containing different ingredients.

Joint FAO/WHO Program on Food Standards

By DR. ERNST ABRAMSON

This Is a Report of the Conference Held in Rome on November 23, 1961. Mr. Abramson Is the Associate Editor for Europe of the FOOD DRUG COSMETIC LAW JOURNAL.

THE JOINT Food and Agriculture Organization/World Health Organization Program on Food Standards aims at simplifying and integrating food standards work now carried on by many international organizations and at providing an effective mechanism for obtaining government acceptances of these standards, together with their publication in a *Codex Alimentarius*.

(2) The Conference felt that these aims could best be achieved by establishing a *Codex Alimentarius* Commission open to all interested member nations of FAO and WHO, which would incorporate and take over the present European Council of the *Codex Alimentarius*. Such Commission would have as primary tasks the determination of priorities and the allocation of preparatory work on each standard to the best qualified outside technical body, CIIA, ISO, specialized nongovernmental organizations, and so forth. This body would submit a draft to the Commission for finalization at the government level, following the well-tried methods introduced by the Code of Principles concerning milk and milk products.

(3) The Conference believed that the present duplication of effort and publication of conflicting standards could thus be avoided, and that substantial economies in time, work and outlay would result. At the same time, the program would provide an appropriate instrument to handle the rapidly growing demands of work in this field.

(4) The Conference was nonetheless aware of the difficulties involved in the establishment of international food standards and called

the attention of the *Codex Alimentarius* Commission to the need to consider the special requirements of individual regions.

(5) The Conference noted that existing Food and Agriculture Organization work on food standards would gradually be integrated into the new joint program. It was understood that in so doing, care would be taken to avoid adversely affecting the methods and progress of the Code of Principles concerning milk and milk products. Work on pesticide residue problems under the Joint Program on Food Standards would depend upon recommendations to be made by the special Conference on the Use of Pesticides.

(6) The Conference therefore adopted the following Resolution:

DRAFT RESOLUTION NO. . . ./61

The Conference

Considering the rapidly growing importance of internationally accepted food standards as a means of protecting consumer and producer in all countries, whatever their stage of development, and of effectively reducing trade barriers;

Recognizing the need to simplify and integrate international food standards work so as to avoid duplication and conflicting standards and to effect economies in effort and outlay;

Desiring to achieve these aims and to harmonize the special requirements of regional markets with those of the international food trade in general;

Conscious of the importance of the role of the World Health Organization in all health aspects of food standards work;

Endorses the proposals, submitted by the Director-General on the request of the First FAO Regional Conference for Europe, for a Joint FAO/WHO Program on Food Standards (C 61/53);

Decides to establish, in accordance with Article VI of the Constitution, a *Codex Alimentarius* Commission, whose statutes are set out in the Appendix to this Resolution;

Urges all interested Member Nations to contribute to the special Trust Fund by which, subject to review by the 12th Session of the Conference, the program will be financed, and to consult with the Director-General as to the amount of their contributions;

Requests the Director-General:

(a) to draw to the attention of the Director-General of WHO the importance attached to an early endorsement by that Organization of the present proposals for a Joint FAO/WHO Program on Food Standards;

(b) to implement the program as soon as sufficient funds have been received and, in consultation with the Director-General of WHO, to call the first session of the *Codex Alimentarius* Commission, if possible by June 1962.

APPENDIX

Statutes of the Codex Alimentarius Commission

(1) The *Codex Alimentarius* Commission shall, subject to Article 5 below, be responsible for making proposals to, and shall be consulted by, the Director[s] [1]-General of the Food and Agriculture Organization (FAO) [and the World Health Organization (WHO)] on all action to be taken in the undermentioned fields:

(a) Promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations;

(b) Determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;

(c) Finalizing standards elaborated under (b) above and, after acceptance by governments, publishing them in a *Codex Alimentarius*,[2] together with international standards already finalized by other bodies under (a) above, wherever this is practicable;

(d) Amending published standards, after appropriate survey, in the light of developments.

(2) Membership of the Commission is open to all Member Nations and Associate Members of FAO [and WHO] which are interested in international food standards. Membership shall com-

[1] All provisions shown in brackets [ ] are subject to endorsement of the proposed Joint Program by the World Health Organization.

[2] In order to accelerate the pace of the work and to take account of the rapidly integrating European market, acceptance of any standard by European governments will, during an initial period of four years, be a necessary and sufficient condition for its publication in the *Codex Alimentarius*.

prise such of these nations as have notified the Director-General of FAO [or of WHO] of their desire to be considered as members.

(3) Any Member Nation or Associate Member of FAO [or WHO] which is not a member of the Commission but has a special interest in the work of the Commission may, upon request communicated to the Director-General of FAO [or WHO, as appropriate], attend sessions of the Commission and of its subsidiary bodies and *ad hoc* meetings as observers.

(4) Nations which, while not Member Nations or Associate Members of FAO [or WHO], are members of the United Nations, may be invited on their request to attend meetings of the Commission as observers in accordance with the provisions of FAO [and WHO] relating to the grant of observers status to nations.

(5) The Commission may establish such subsidiary bodies as it deems necessary for the accomplishment of its task, subject to the availability of the necessary funds.

(6) The Commission may adopt and amend its own rules of procedure, which shall come into force upon approval by the Director[s]-General of FAO [and WHO], subject to such confirmation as may be prescribed by the procedures of the[se] Organization[s].

(7) The operating expenses of the Commission and of members of the secretariat[s] of FAO [and WHO] directly serving it, shall be defrayed by a special Trust Fund administered by Food and Agriculture Organization [on behalf of the two Organizations] in accordance with FAO Financial Regulations. Contributions to the Trust Fund from participating countries shall be accepted only through or with the approval of the government concerned. At the end of each year unused sums shall be returnable to contributors or carried over to the following year.

(8) All expenses involved in preparatory work on draft standards undertaken by participating governments, whether independently or upon recommendation of the Commission, shall be defrayed by the government concerned. **[The End]**

Food Additives and Hazardous Substances

By JOHN L. HARVEY

Mr. Harvey Is Deputy Commissioner of the Food and Drug Administration, Department of Health, Education and Welfare. This Paper Was Presented at the Seventeenth Annual Meeting of the New York State Bar Association — Section on Food, Drug and Cosmetic Law, Which Was Held on January 24 in New York City.

I THINK anyone who suggests that a representative of the Food and Drug Administration discuss the topic of "food additives" is taking quite a risk, because we feel so strongly that this amendment affords the consumer real protection that we are tempted to take every opportunity to tell people all about the amendment and how it works. I realize, however, that such a discussion is not called for as far as this group is concerned, and I will therefore limit my remarks to a few special circumstances.

I think initially we should admit that the problem of evaluating food additives and getting out the necessary regulations was grossly underestimated both by industry and the Food and Drug Administration, and this is especially true in the area of the so-called indirect additives. We have had problems in this area and so has industry. I should pay tribute to the patience and understanding of the many industry groups and individuals who have been involved in this work.

For the Food and Drug Administration's part, our people have, in my opinion, been doing a heroic job in going over petitions, attempting to assist industry people in getting the necessary information, and doing the myriad of other chores in connection with this work. Very frankly, the principal trouble as we see it is that we just don't have enough scientists to handle these matters with the expediency to which, in our opinion, they are entitled.

We have been criticized in some quarters for our advocacy and support of the legislation enacted last year to authorize further extensions of the effective date of this amendment. Nevertheless, we are

convinced that this legislation was needed and that we were right to advocate it. We can, however, unqualifiedly state that we know of no instance where the amendment has authorized continued use of the food additive which may present an undue hazard to the public health during the period of extension and that no such extension ever will be granted knowingly.

While I am on the subject of extensions, I would like to point out what may not be immediately apparent—this is the requirement that any extension beyond January, 1962 is conditioned on the submission of a progress report at six month intervals and that if we do not receive a progress report on the due date or if the progress report is not a satisfactory one, we will have no alternative but to cancel the extension for the product involved forthwith.

It has been extremely interesting to me to note a change in attitudes not only on the part of some industry people, but of many consumers as well, as the Food Additives Amendment became better and better known. Shortly after the enactment of this legislation, it seemed to me that there was, on the part of many, an objective to find some way by which their particular products could be classed as exempt from the amendment, either through getting them on the generally recognized as safe list, finding that someone else had a prior sanction for the particular formulation, or, in the case of indirect additives, showing that there was no migration of the particular components to the food. Recalling the advertising of a certain cigar a few decades ago, it seemed then as though many people in industry regarded the term "food additive" as a horrid word.

Change in Attitude

I am convinced that this attitude no longer prevails. This is shown by the zeal with which industry people, including many of the associations, have come forward to try to supply the necessary information to obtain an authorizing regulation. Additionally, we now find that some people with perfectly valid prior sanctions are requesting that we include the prior sanctioned items in formal regulations so that these will be out in the open for all to see that their products have had adequate study and that we agree that they may be safely used under specific conditions.

Undoubtedly part of this change in attitude is due to the fact that both industry and the Food and Drug Administration have achieved

success in their efforts at consumer education about food additives, what they are and why they must be found to be safe before they can be used.

Certainly, we still receive occasional letters from some individuals who have read published articles tending to suggest that the food industry and the Food and Drug Administration are engaged in an unholy alliance to poison the American public, but these are definitely in the minority and the facts clearly prove otherwise.

There seems to have been difficulty in some areas where a single food additive is manufactured by a number of different firms. As one of our people put it, each of the group seems to feel that the other fellow should be the one to "bell the cat." The Food and Drug Administration does not care whether a petition for a food additive regulation is submitted by a single firm or by a group of firms. Occasionally, some of our people have suggested that perhaps the best way to proceed would be for the various manufacturers to get together. Almost invariably, the first reaction is that any such collaboration might well result in conflict with the antitrust laws. We in the Food and Drug Administration do not pretend to be experts in the antitrust field. We do know, however, that groups of manufacturers have banded together for the purpose of seeking authorizing regulations and we have yet to hear of any antitrust difficulties which resulted from this objective. Perhaps anyone who agrees that such a group effort would be the desirable course might take the trouble to discuss the proposal with the Department of Justice people as an added safety measure. The fact remains that if a substance is a food additive, it must have an authorizing regulation if it is to be continued to be used. On presentation of the necessary data, we will do our part.

Some two years ago, I heard comments to the effect that the issuance of a food additive regulation could well serve to stifle progress as far as the particular article involved was concerned. A study of the regulations which have issued to date shows that a substantial number of these have been amended to provide for new authorizations. Some of these have been amended more than once and I think it is generally agreed that it is probably easier to get an amendment to an established regulation than to get the basic regulation in the first place. So I am sure that no one need have any fears on that score.

As you know, each food additive order includes a provision for the filing of objections and requesting a public hearing thereon based

on reasonable grounds. We have had a significant number of objections filed to a number of the food additive orders so far issued and, by and large, the views expressed have been helpful to us. In the case of some objections, we have been able to amend the regulations to satisfy the objections. Where we could not do so, we have written to the objector, pointing out why we could not follow the course suggested.

It is gratifying to me that, so far, this has not resulted in any requirement for the holding of a public hearing, but if a situation calling for one in this field arises, it will be our purpose to call such a hearing at the earliest possible date. I believe that some of the objections dealing with the labeling requirements of the regulations have been based on a misunderstanding. We have no intention of using the food additive regulations to call attention to the other provisions of the law. We include in the food additive regulations only such labeling requirements as are necessary for the safe use of the additive involved.

I want to reiterate that in the food additive field, as with other areas in which the Food and Drug Administration is concerned, our doors are always open. We invite you to come to us with your problems and we assure you that we will give you the best advice possible to enable you to comply with the terms of the amendment and the basic law. On the other hand, no one should lose sight of the fact that the Food and Drug Administration is a regulatory agency and that when we find violations, including violations of the Food Additives Amendment as we already have, it is our obligation to take appropriate action to correct those violations.

I say again we think this is a splendid law. It is working, and we want to make it work better so that the American consumer may continue to have justifiable confidence in the safety and integrity of our food supply.

Hazardous Substances Labeling Act

Now I would like to shift a bit and make some comment about the Federal Hazardous Substances Labeling Act.

It might be profitable to review again the fundamental facts about this statute and of the rulemaking developments since it was passed. There may even be in this audience a few to whom the subject will be a new one.

The Federal Hazardous Substances Labeling Act was enacted by Congress on July 12, 1960. Its passage represented cooperative effort

by members of the medical profession, industry associations and the Food and Drug Administration. The impetus behind its passage was a realization on the part of all concerned that modern technology had rendered obsolete the Federal Caustic Poison Act. This earlier statute, which was enacted in 1927, was designed to warn, by proper labeling, users of twelve specific substances found around the household which had become implicated in more and more poisoning incidents. Such things as carbolic acid, sodium hydroxide and silver nitrate in certain percentage ranges are examples of the products covered by this act. But modern technology has developed cleaners, adhesives, solvents, polishes and a myriad of other household products which, when used according to directions, are perfectly safe, but when misused by adults or abused by inquisitive children result in injury and suffering. The Federal Hazardous Substances Labeling Act, therefore, is intended to broadly cover household aids and require them to be prominently and conspicuously labeled with the fact that they are hazardous. The act requires the manufacturer to list on the label the name of any poisonous ingredient, and other information which would be helpful to doctors treating an injured child, and certain other precautionary labeling directing the user or parent to properly use, store and handle a potentially dangerous substance.

The act parallels in a great many respects the civil, criminal and injunction provisions of the Food, Drug, and Cosmetic Act as such action would apply to a misbranded article. It includes the same factory inspection authority and prescribes the same kind of import responsibility and authority as does the Food, Drug, and Cosmetic Act.

The Federal Hazardous Substances Labeling Act specified that no civil or criminal sanction would be enforced until six months after passage and granted the Commissioner of Food and Drugs an additional 12 months of administrative authority to suspend these sanctions either specifically or generally as the conditions warrant. On February 1, 1961, the Commissioner suspended for six months the civil and criminal sanctions of the law as they applied to all types of hazardous substances except highly toxic, extremely flammable and flammable liquids. At the end of this six months period he further suspended the same provisions until February 1, 1962.

Substances are hazardous under the terms of this statute if they are toxic, irritant, corrosive, strongly sensitizing, flammable, or if they generate pressure through heat, decomposition or other means,

and if such substances or mixtures of substances produce substantial injury or illness as a proximate result of reasonably foreseeable handling or use, including ingestion by children. To come under the purview of this statute a product must be in a container "intended or suitable for household use." We have had some difficulty with our interpretive definition for containers intended or suitable for household use to the satisfaction of firms who produce primarily for industrial use, but whose products may reach a home and its environs.

We have been asked rather frequently to exempt a whole line of products from compliance with the statute because they are produced primarily for industrial use. We have not been able to make any such sweeping exemption. We have granted that products labeled, marketed and used for industrial purposes do not require labeling under the Federal Hazardous Substances Labeling Act. On the other hand, merely labeling a product "for industrial use" does not provide a basis for not labeling products in compliance with the statute.

On August 12, 1961, we published in the *Federal Register* rather comprehensive definitive and interpretive regulations which we felt were necessary for orderly compliance and enforcement of this important consumer statute. These final regulations were enacted after rather stormy response to proposed regulations published in April. One of the most important decisions made in connection with the regulations was the definition of a substance toxic by ingestion as one which would produce in a group of test animals death in one-half or more than one-half when fed at a single oral dose of 50 mg/kilo of body weight of test animal. It was argued that a much lower dose would be a preferable level, and that many products which would be toxic to animals at a dose of five gm/kilo actually presented no practical hazard in the laboratory of human experience.

The act itself provided the resolution to these differences of opinion. The framers of the legislation were aware that there would be instances where products would meet laboratory tests as hazardous substances, but for various reasons might not be hazardous to people. They therefore provided that when it could be found that because of the size of the package, the minor hazard presented, or for other good and sufficient reasons the public health and safety did not require all of the labeling required by the statute, the Commissioner could by regulation grant exemption from such labeling. We have developed an informal petition system and invite those who have the responsibility for labeling household products to submit reliable data indicating

that even if certain products are hazardous by the animal tests they are not hazardous in actual use. Under this exemption procedure we have granted modified labeling to boxes of ammunition, and exempted from the required labeling for ball point pen ink cartridges and refills when they meet certain specifications. We have several more petitions under consideration at this time which, if granted, would provide relief for rather large segments of industry.

Improper Labeling of Distributed Stock

There has been much discussion about the attitude of the Food and Drug Administration about stocks of products which will be in various points of the distribution pipelines on February 1. We have also been petitioned to suspend the provisions of the act and the regulations to give time to industry to change over their many labels. We have no authority whatsoever to extend beyond February the provisions of the statute itself. Congress alone can do this. We do have authority to adjust the effective date of implementing regulations if we do not by so doing contravene the clear intent of the law. We would not be justified in exercising this authority unless the consumers' interest was not thereby jeopardized.

When containers of products which are hazardous under the terms of the law are not properly labeled on February 1, 1962 they are subject to the seizure provisions of the statute. Containers of products under the law which are shipped in interstate commerce after February 1 will be subject to the seizure provisions of the act and the shippers subject to the criminal provisions.

The administrative authority of the Commissioner to suspend these sanctions expires on February 1, 1962. There is before Congress a bill to extend this administrative authority for an additional 12 months. We have no way of predicting the outcome of this legislation. In the matter of postponement of regulations we very carefully considered what we might do in this regard while still maintaining our responsibility to Congress and the consumer to enforce this public health statute. We saw no good reason to suspend the effective date of the definitive regulations, nor those administrative regulations dealing with procedures or of those dealing with imports. We did agree that if labels of hazardous substances complied with the statute it would not be necessary for the required statements to be on the labels with the placement and type size requirements which were specified in the regulations. These requirements were therefore suspended until

August 1, 1962. We believe that this suspension will provide a measure of relief which should greatly assist industry during the period that they are changing over labels.

We also provide in our regulations a statement of policy that in lieu of complete change-over of labels we would not object to the application of sticker labels to provide the necessary labeling even though it might not meet the letter of the regulations.

We are not unmindful that labeling problems do exist. It will be our intention to enforce this statute reasonably. We do intend to be reasonable also from the consumer standpoint and to do our best to provide in an orderly manner and as soon as possible adequate warning labeling to users and parents of small children. We hope these measures will rapidly bring to a minimum injury and illness caused by accidental exposure to household aids. **[The End]**

FALSE CLAIMS ON LABELS

Beauty Power "skin-toner" device and Fountain-Facial face-cleanser powder have been seized on Food and Drug Administration charges of false and misleading label claims.

Almost 200 "Beauty Power" devices, shipped by Sylvania Electric Products, Inc., Muncy, Pa., were seized in possession of the dealer, Beauty Power, Inc. (Contour Chair Lounge Corporation) New York, N. Y. The device gives the skin a tingling sensation by means of wet pads connected to a small power transformer. FDA charged that the labeling made false claims that the device was effective for revitalizing and restoring resiliency to facial muscles; irradiating facial lines; firming sagging facial contours and double chin; toning flabby muscles and making them stronger, more elastic and younger; stimulating circulation in the facial area; relieving tension; removing cropiness of the skin and "dowager's hump"; and improving skin texture. The charges states that the device was neither adequate nor effective for such purposes and is not capable of fulfilling the promises of benefit stated and implied.

Over 18,000 packages of "Fountain-Facial with 'Keroxylite' skin brightener, cleanser, antiseptic," were seized in possession of the distributor, Hopkins Chemicals, Inc., Baltimore, Md. FDA alleged that the labeling of the article falsely represented it as an effective treatment for acne, pimples, blackheads, bacterial infections of the skin, and inflammed hair follicules.

The Packaging and Labeling Hearings

By S. JERRY COHEN

This Talk Was Presented at the Seventeenth Annual Meeting of the New York State Bar Association—Section on Food, Drug and Cosmetic Law on January 24 in New York City. Mr. Cohen Is Counsel for the Antitrust and Monopoly Subcommittee on Packaging and Labeling of Food and Other Consumer Products of the Senate Committee on the Judiciary.

THE EXECUTIVE VICE PRESIDENT of one of America's best known ad agencies recently told an audience of potential advertisers about two men who had been shipwrecked on a desert island for a couple of years. One day a bottle came floating by and one of the men waded out in the surf to get it. It turned out to be a king-size Coke bottle and he came in holding it for his partner to see.

"Good Lord," he said, "we've shrunk."

If the hearings that Senator Hart has been holding for the Senate Antitrust and Monopoly Subcommittee on packaging and labeling practices of market basket items are any criteria, the new larger king size package may also mask shrunken contents.

Problems Facing Consumers

This practice of reducing content without making the fact clear to the buyer has been one of the bones sticking in the threoat of the consumer. And it is not enough to say that this is the work of an industry fringe. From the examples and exhibits we have seen, this is a widespread industry practice.

One economist who testified at the hearings attacked this practice as hidden inflation.

The executive vice president of Scott Paper Company testified that this was a prevalent and a bad practice. He said, "There is room for improvement in the field of package sizes, because in this area a manufacturer may cut the content slightly to get a price advantage

or keep the price to get a profit advantage. Yet the eye appearance makes the package look very alike as to size." He might have mentioned that in many instances, the new package in fact looks bigger.

The business of comparing prices in view of the multiplicity of odd sizes and weights, the difficulty of finding net weight and the chore of wading through the mass of meaningless information on the package is a problem of immense proportions to the consumer.

And this chore is often complicated by the various "cents off" promotions which may or may not be reflected in the retail price. We have seen instances where the product has always been "cents off" or where the "cent off" has been used to conceal a rise in price.

Premiums, meaningless serving phrases and other practices of which you are more aware than we are, have complicated the job of shopping until to do so rationally has become an unduly difficult, if not, impossible task.

As the ad executive put it, "For the first time, we have a buyer who has a job that is too big for him. He has too many products to choose from, too many brand names to learn, too many needs to satisfy. Yet he is equipped with no larger brain cavity, no more highly developed set of memory nerves than before . . ."

Yet what is basic to a free competitive system is that the consumer must make a rational choice, or at least have a reasonable shot at it, if he wants to.

This is what our hearings are all about.

In this exploding prepackaging area, the problem of getting essential information takes on added urgency because of this same growth. Today there are approximately 8,000 items in the average supermarket, the great majority of which are prepackaged. In the next decade, it has been estimated there will be 20,000 such items.

And where does the shopper get the essential information about the products? There is no salesman, no explanatory literature, no groups or agencies evaluating the contents. The sources of information are two—the package and the advertising. Unless we want to talk about requiring essential information in advertising, only the package remains.

I can't emphasize too strongly the fact that the shopper can look only to the package itself as the spokesman for the manufacturer to get the information he needs to carry out his obligation in a free enterprise economy to shop rationally.

I stress this only to demonstrate that the focus of Senator Hart's inquiry is based on this premise of rationality that is basic and elemental in our economic system—as basic and elemental as how much is in the package and how much is being paid for it on a per unit basis.

What possible objection can there be to guaranteeing that the shopper be given this basic information by the manufacturers's representative on the shelf—the package—in a manner that is readily observable and readily understood.

The question of quality is not involved. If the customer wants to pay more or less for a particular commodity based on quality, fine. But first, this question must be answered. How much more, or less am I paying for this product compared to its competitors on the shelf?

What industry can legitimately object to is that in devising a serum to cure the ill, we trigger side effects more harmful than the original disease. This is a proper area of concern, particularly by the group here. All I can say is that Senator Hart is well aware of the problems in devising appropriate legislation and there is no intention to strait jacket or significantly restrict industry flexibility.

There *is* an intention to devise legislation that will help guarantee that the consumer can get this basic information from the package in a way that can be reasonably determined.

Two basic objections have been made to possible legislation. First, that the subject matter is too complex to lend itself to legislation. Second, that self-regulation is the most effective answer to the abuses that admittedly exist.

As lawyers, you know that the argument that a subject matter is too complex for legislation is in reality a straw man. Most subjects of legislation are complex—particularly in this complex society. To say that a subject is too complex for legislation misses the point of our legislative system. Complexity means only that greater care must be taken in devising the legislation. Frankly, and I think you would all agree, this subject matter is no more nor less complex than the many other subjects about which legislation is passed each year.

Sometimes uncertainty as to what can be done within present law is confused with complexity of subject matter. It may well be that the present law is not adequately drawn to cover the growth or advances of the past ten years, or the projected growth or advances of the future.

What manner of packaging and labeling of foods and drugs and cosmetics is now permissible under the present law is difficult to determine. The extremes are not so difficult to determine. But that great gray area of what is or is not "conspicuousness," and "not misleading" for instance, is often a matter of whim rather than a question of certainty. Do any of you consider there are clear guides by which you can safely advise your clients. I submit that too often what is allowable depends on the zeal of the enforcing agency and the attitude of the court that might be involved.

In this area of packaging and labeling, does the establishing of reasonably definite standards with flexibility for exceptions where necessary complicate or simplify the situation? And what about those nonfood, drug and cosmetic products that compose 40 per cent of the profits in the average supermarket?

There is no law covering them whatsoever. Yet you dare not take the chance of advising that no content designation be put on the package. The FTC could conceivably become interested. What guide do you have for advising your client in this area?

The law to be effective must combine both certainty and flexibility. Administrative whim and legal guesswork are not a fair substitute.

In regard to self-regulation, in this vast $70 billion a year industry covering so many products, sold in so many outlets, self-regulation is difficult, if not impossible.

Without sanctions, self-regulation is difficult. In an industry as highly competitive as the food industry with profit margins so notoriously low, self-regulation becomes virtually impossible. It is significant that a start has been made by the Cereal Institute. It is more significant that to date, the cereal manufacturers stand virtually alone in attempting self-regulation.

Wouldn't it be fairer to all concerned, the consumer, the manufacturers and their harassed lawyers, if the merchandising battle could be fought within definitive ground rules that would make product superiority and price advantage, instead of gimmick inventiveness, the thrust of the sales campaign?

You are sure to be disappointed in what I have said today. I know that you hoped to get from myself and Mr. Williams some idea of what type of legislation is in mind. However, when Senator Hart stated that no legislative proposals would be considered until all the

testimony had been completed, he was stating a policy that he has laid down to which we have all adhered. So I cannot tell you what legislative proposals you can look forward to, or askance at, simply because there presently are none.

Further, although you may be slightly skeptical, Senator Hart's mind is completely open to any ideas any of you may wish to propose that have as their end the simplification of the task of buying. We welcome your ideas. They will actually be given careful consideration.

I hope you have sensed by the manner in which the hearings are being conducted that we do not intend to be stampeded into hasty or ill-conceived legislation. On the other hand, we are not prepared to accept the status quo.

The economics, the mortality, the realities of the situation demand appropriate action. The consumer and ethical manufacturer the retailer and wholesaler alike need legislative assistance to better perform their respective jobs in this free economy.

With your help and that of other affected parties, we hope to do a legislative job that will benefit all and shackle none; that will be definitive yet flexible; that will simplify, rather than make more complex. **[The End]**

PROPOSED RESTRICTION OF PERNICIOUS ANEMIA DRUGS

The Commissioner has announced a proposed general statement of policy on the misbranding and adulteration of preparations for the treatment of pernicious anemia. The policy statement would provide that any drug which contains, or purports to contain, intrinsic factor or intrinsic factor concentrate will be regarded as misbranded unless labeled with the legend "Caution—Federal law prohibits dispensing without a prescription". Any drug intended for oral ingestion in the treatment or prevention of pernicious anemia, or which contains, or purports to contain, intrinsic factor or intrinsic factor concentrate will be regarded as misbranded unless labeled with legend "Caution—This preparation is not a reliable substitute for parenterally administered cyanocobalamin (vitamin B_{12}) in the management of pernicious anemia. Periodic examinations and laboratory studies of pernicious anemia patients are essential."

In addition, the statement would provide that, since intrinsic factor and intrinsic factor concentrate are food additives, any food containing these substances will be regarded as adulterated. Interested persons may submit their views on the proposed regulation by March 15, 1962. FOOD, DRUG, COSMETIC LAW REPORTS—Regulations, ¶ 1011.

Report From the Food and Drug Administration

By M. R. STEPHENS

The Author Is the Director of the Bureau of Enforcement, Food and Drug Administration, Department of Health, Education and Welfare. He Delivered This Talk at the Meeting of District Number Two of the American Association of Colleges of Pharmacy and National Association of Boards of Pharmacy on November 3, 1961, at Williamsburg, Virginia.

WHAT IS THE SETTING in which the pharmacist and the regulatory official find themselves today in their joint effort to ensure the integrity of the national drug supply?

Briefly it is this. The annual sales of prescription drugs have jumped from $200 million in 1939 to over $2½ billion today. It is stated that the cost of drugs is now 20 per cent of the total bill for medical care in this country. We have witnessed the development of a wide variety of new drugs; 90 per cent of the prescriptions are written today for drugs not on the market 20 years ago. There has been an amazing revolution in the drug field in the last two decades that has contributed enormously to combating ill health and has been a major factor in the dramatic advances of medical science.

Clearly, in this scheme of things the pharmacist plays a most vital role. His responsibility as the custodian and dispenser of our national drug supply is both great and grave.

What does this stewardship entail and how good has it been? A full exploration of the question could lead us into a discussion of the pharmacist's obligations from the standpoint of the ethics of his profession as well as his obligations under state and federal law.

The matter of ethics of the pharmacist we leave to the leadership of your profession. The teachers of pharmacy have made, over the years, and are continuing to make, a tremendous contribution in this

field. We commend you for your untiring efforts to imprint on the minds of the pharmacy student the basic concepts of public service and responsibility.

The matter of compliance with state law we leave to the Boards of Pharmacy and other duly authorized state agencies. As we go forward in our regulatory programs in the prescription drug field we are establishing a closer working relationship with our counterparts on the state level. Strong regulatory programs are being carried on in a large number of states. This is helpful and encouraging to all who share responsibility in this great field.

Pharmacist's Responsibility

I would like today to talk specifically about the responsibility of the pharmacist under the terms of the Federal Food, Drug, and Cosmetic Act. However, from many discussions I have had with responsible leadership in your profession, whether as operating pharmacists, teachers or regulatory officials, I can only conclude there is one common goal sought by professional ethics and by law: to ensure the integrity and safety of the drugs that are put into the hands of the sick. This is a most worthy goal and a tremendous task for each and all of us in our respective fields.

Our first obligation and consequently our number one step is to see that drugs as manufactured and delivered to you are of unquestioned composition and safety as well as honestly and informatively labeled.

Once proper manufacturing and labeling is achieved and the drugs have moved in proper channels to those authorized by law to handle them, we must then look to the pharmacist to safeguard the drug until it gets to the user. As you know, the federal law, as written and interpreted by the courts, clearly intends that the integrity of the drug be assured all the way to the patient's hands.

How does the pharmacist make certain that the drugs he buys are of unquestioned composition and properly labeled? He buys properly packaged and labeled drugs from known, established, responsible people in the drug business. In this connection we have stepped up our rate of inspection of pharmaceutical manufacturers and the sampling and analysis of their products. We expect this year to examine more than twice as many samples representing the output of the drug industry as were examined last year. We are taking a

closer look to see that methods of manufacture and labeling practices on new drugs are consistent with the methods and practices described in the effective new-drug application.

We have made basic changes in the regulations dealing with the labeling of prescription drugs. As you know, in September, 1961, we issued in final form a regulation requiring each prescription drug (except those whose uses and contraindications are commonly known to doctors) to bear full directions and any necessary warnings.

Here are some other measures we have taken to ensure the integrity of the pharmacist's basic drug supply and to protect him from those who would sell him spurious, or worthless drugs.

Protection Against Counterfeit Drugs

Legal actions have been stepped up during the past year against counterfeit drugs. Counterfeiting has been a recurrent problem through the years and one of varying intensity. We had to bring criminal actions in the early 1950's to break up a counterfeit racket. In the past couple of years we have had to renew our control efforts.

The drugs which are usually selected by the counterfeiters are the well-known, widely-prescribed, large volume products. They are made in such precise imitation of the genuine articles that differences are discernable only by specialized techniques of microscopic, ballistic, or chemical examination. I am sure you recognize that the danger in this situation is that the counterfeits of important medications do not pass through the safety clearances or manufacturing control procedures necessary to assure a safe product that complies with the Food, Drug, and Cosmetic Act.

Early this year, cooperative efforts of the New Jersey state officials, the Department of Justice and the Food and Drug Administration resulted in charging the General Pharmacal Company of Hoboken, New Jersey with the manufacture and distribution of counterfeit drugs. All indications are that this firm was the nucleus of the counterfeit drug racket with nationwide distribution. Extensive surveys by the Food and Drug Administration during the past two years have linked all of the counterfeits whose origin has thus far been determined with General Pharmacal. Two thousand seven hundred samples collected at 900 drugstores in February and March disclosed nine samples of counterfeits from nine different stores. We believe that curtailing the operations of this manufacturer and dis-

tributors of its output has broken the backbone of the major counterfeit drug racket in the country. But we still recognize the potential hazard and intend to vigorously pursue wiping out this racket whenever it springs up.

Although the center of distribution of these counterfeit drugs was a wholesale druggist, we are happy to report that wholesalers generally did not take part in this fraudulent operation.

This fact should also be very gratifying to the pharmacist for it means that if he is reasonably prudent in the conduct of his business he need have no fear of becoming an unwitting partner with the counterfeiter in carrying out his nefarious scheme.

What made this surge of counterfeiting possible? The answer is very simple. A number of pharmacists, in hopes of a quick dollar were willing to ignore the ethics of their profession and flaunt the law by engaging in this evil and dangerous practice. There may be some who were unwitting and innocent victims of the counterfeiter. However, we find it difficult to accept at face value pleas of good faith by the pharmacist charged with dealing in counterfeit drugs when we have evidence he has bought for a price, outside the ordinary and usual channels, and when delivery of life-saving types of drugs has been made under the counter to him in partially or entirely unlabeled cellophane and paper bags and other such unorthodox containers.

Illegal Use of Physician's Samples

Another matter to which we have devoted a great deal of time in recent months is the campaign against the mishandling of physician's samples. The abuses which we encountered came to light as an outgrowth of our investigations concerning counterfeit drugs.

You are well aware of the widespread practice of furnishing physicians with drug samples. However, some of you may not be as well aware of the practices which have grown up primarily because physicians do not want many of the drugs they receive. These so-called "waste basket" drugs have been collected by repackers who destroy the essential labeling and then market the repacked drugs to retail pharmacists. Investigations of these operations have resulted in some 40 seizures in recent months and some of them involved many thousands of dollars worth of merchandise.

Our survey in this area has uncovered gross carelessness in the handling of extremely potent and life-saving drugs.

Our inspectors have reported abuses such as:

(1) Disregard for the expiration dates of antibiotics.

(2) Mix-up of drugs not only as to identity but also with respect to strength.

(3) Destruction of essential labeling containing directions, warnings and precautions for the safe and effective use of the drug.

Inspectors have reported several instances where firms had drugs intended only for investigational use on their shelves. They were labeled: "Caution: Limited by United States law to investigational use". Distribution of such drugs is legal only to persons conducting research.

As a result of the finding of such serious abuses Commissioner Larrick made the following recommendations:

(1) Pharmaceutical manufacturers curtail and control the distribution of physician's sample drugs and supply physicians only with the drugs they want and will use.

(2) That the medical profession through its medical societies request their members to stop accepting physician's samples unless they intend to use them in their practice and to destroy all samples they do not use so they will not be diverted from their intended use.

(3) That physicians and representatives of pharmaceutical manufacturers (detail men) discontinue distributing physician sample drugs to retail pharmacists for dispensing.

(4) That pharmacists discontinue using physician's samples to fill prescriptions.

(5) That drug firms immediately check on their systems of accounting for new drugs for investigational use to be certain that any not used in clinical investigation are destroyed.

(6) That physicians and others engaged in the evaluation of new drugs destroy any stocks of investigational drugs not used.

The Food and Drug Administration has no objection to drug manufacturers furnishing pharmacists with free prescription drug samples but recommends they do so by supplying pharmacists with fully labeled and packaged products and not with physicians' samples.

A number of druggists have voluntarily destroyed physicians' samples when Food and Drug Administration inspectors pointed out that they were not intended to be sold.

We have had outraged cries from some, who in the name of pharmacy, have protested our physician's sample program and the manner in which they have heard it is being carried out.

Perhaps it might be argued that our view about the inappropriateness of original packages of physicians' samples being in possession of, and used by, the pharmacist in filling prescriptions is not sound. This is a legal question for the courts to pass on but in any event to dwell on this rather isolated and somewhat trivial question is to fail to recognize the real seriousness of the practical aspects of the way physician samples have been handled. If I were to outline in detail some of the conditions we have found, I think there would be no denial by anyone of you that there have to be some changes made.

Now, as to the manner in which the program is being carried out by our inspectors.

We have had a number of reports, we assume all in good faith, of improper, if not outright illegal conduct by our inspectors. Believing them to be made in good faith by responsible people, we here, like we do in all such situations, had a careful check-up made to ascertain the facts. In no instance were we able to substantiate the charges.

Let me hasten to add, however, that this is not to be taken as a brush-off for any future complaints. If you, on the basis of facts known to you or known to any other responsible person, have reason to question the conduct of a Food and Drug Administration employee we urge you to bring it to our attention. We assure you it will be carefully investigated. Charges of misconduct from a responsible source are not taken lightly by us.

All of those regulatory steps I have mentioned are designed to give confidence and protection to the ethical pharmacist in his drug purchasing and dispensing and most of all to assure that the patient is going to get the drug the physician has ordered for him.

However, the responsibility of the Food and Drug Administration does not end at this point. We have the responsibility to see that prescription drugs are turned over to the patient only upon the specific order of the physician. This is what the Durham-Humphrey Amendment of the Act requires.

After several years of enforcement of this Amendment we still find a sizeable number of pharmacists who are willing to sell prescription drugs without a doctor's order.

This past year 144 criminal cases were terminated. Sixty-two involved drugstores and pharmacists. The remainder, for the most

part, were unlicensed or unauthorized outlets such as cafes, truck stops, peddlers, etc., with some physicians who were more interested in peddling drugs than in the bona fide practice of medicine.

Seventeen individuals, including three pharmacists, were sent to jail and material fines and probation were imposed in other cases. In terms of the pharmacy profession we unquestionably are seeing an improvement. In the terms of the over-all problem, with particular reference to the illegal distribution of amphetamines, we are not as sanguine. We have seized hundreds of thousands of the so-called "pep pills" and stiff sentences have been imposed against offenders but the operation seems to go a little deeper underground and continues to flourish in spite of the considerable manpower we have put on it. The lure of the quick and easy dollar is great.

With some better regulatory tools and with a growing recognition by the courts of the seriousness of the health hazard involved in this pill peddling we eventually, with the help of your profession and the state regulatory officials, will be able to cope with the problem. Unless we move vigorously and with dispatch it is not unreasonable to expect that we may have more highway accidents attributable to the misuse of amphetamines.

I know that you as leaders in pharmacy will agree that every reasonable safeguard must be used to assure the integrity of our drug supply. No one group or organization can do the job alone. The gravity of our problems in this area behooves us to work together in the fullest practical sense to achieve our common goal. The hour is late. **[The End]**

"FULL DISCLOSURE" EXEMPTION

The Food and Drug Administration recently announced that drugs subject to new drug applications or requiring certification will also be considered for exemption from the "full disclosure" package information regulations when information about them is commonly known to medical practitioners.

The "full disclosure" regulations, adopted last September, permitted such exemptions only for drugs not subject to the new drug or certification requirements.

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.

Animal Feeds Under Federal Law

By CHARLES G. DURBIN

The Author Is the Veterinary Medical Director of the Division of Veterinary Medicine, Food and Drug Administration, Department of Health, Education and Welfare. This Speech Was Delivered at the Texas Nutrition Conference, College Station, Texas on October 5, 1961.

I WAS DELIGHTED to accept on behalf of the Food and Drug Administration the invitation to come to Texas and discuss with you briefly some of the problems facing the feed industry, the farmer and the Food and Drug Administration under the provisions of the Federal Food, Drug, and Cosmetic Act. Let me hasten to point out that this is not a prepared speech in the sense that I will stick to the complete text which I have before me. I would like to read parts of it and comment as I go along and at the end I will attempt to answer some of the questions which I am sure this presentation will leave unanswered.

Technological developments in the animal feed industry require both the state feed-control officials and the Federal Food and Drug Administration to devote an ever increasing amount of time to it. Traditionally the state feed-control officials have taken the initiative and leadership in the regulation of animal feed. While working closely with the state officials through past years, federal officials have remained more or less in the background. The state of Texas has had a very active program under the Texas Commercial Feed Control Act of 1957. Most state officials have been primarily responsible for assuring feeders that feeds they have bought were properly prepared and accurately labeled. Until only about ten or 12 years ago, regulatory activities under federal law were largely limited to actions designed to supplement the work of states, particularly in those cases where the broader jurisdictions of the federal law were needed to implement state action.

Up to this time, an animal feed had been an uncomplicated article consisting simply of products of the soil used as a source of nourishment. The application of the entire Federal Food, Drug, and Cosmetic

Act to such products could be discussed exhaustively in a few paragraphs. Scientific developments in the production of livestock and poultry and the advent of medicated feeds have required numerous changes in the pattern of control just as they have in the formulation and production of animal feeds.

Let me briefly outline the most significant sections of the Federal Food, Drug, and Cosmetic Act that affect the feed. The first federal act was passed in 1906. Administrative experience soon disclosed gaps in the protection afforded by the 1906 act. After a long legislative history a new act was adopted, the Food, Drug, and Cosmetic Act of 1938. We are now functioning under the Act of 1938 and its various amendments.

Before discussing the various sections some definitions are necessary. The term "food" is defined to mean, in part, "articles used for food or drink for man or other animals"; and I wish to emphasize *or other animals* because this is a very important point in the discussion to take place. The term "drug" is defined, in part, to mean "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"; and "articles intended to affect the structure or any function of the body of man" and again "or other animals."

With these two basic definitions, as taken from the act, I believe we are in a position now to discuss some of the other terms used which apply more directly to the feed manufacturer and/or distributor. We use some of the following daily and we sometimes fail to understand why they seem so foreign to other people. One of these terms is "new drug" which is defined in the act, in part, as follows: "Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, ..." In other words, new drugs are those drugs for which the safety, because of the short time in use or in new types of use, has not been completely established. Before feeds containing new drugs can be marketed in interstate commerce, there must be on file with the Food and Drug Administration an effective new drug application for the particular feed.

Form FD-356

Before the Food and Drug Administration may permit new drug applications to become effective, evidence relating to the safety of

such a drug along with the adequate data of research involving it is required. Just recently a revised Form FD-356 became available. This is the form used by firms for submitting new drug applications. At this point, I would like to outline the pertinent points covered by this form, each of which is explained in detail on the form.

(1) Full reports of all investigations that have been made to show whether or not the drug is safe for use.

(2) A full list of the articles used as components of the drug.

(3) A full statement of the composition of the drug.

(4)(a) A full description of the methods used in the manufacture, processing and packing of the drug. (b) A full description of the facilities and controls used for the manufacture, processing and packing of the drug.

(5) Samples of the drug and articles used as components.

(6) Five copies of each label and other labeling to be used for the drug.

(7) A statement as to whether the drug is (or is not) limited in its labeling and by this application to use under the professional supervision of a practitioner licensed by law to administer it.

(8) If this is a supplemental application, full information on each proposed change concerning any statement made in the effective application.

(9) It is understood that the labeling and advertising for the drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application, ...

This new form, in which the most recent changes are included, became effective on May 27, 1961, and requires four typewritten pages to explain the various requirements. I have a few copies of these with me, if anyone is interested, and I am sure that most of you have seen this reproduced someplace or another recently. New drug applications are made effective on the basis of safety and each part of the new drug application has its effect on the safe use of the product. Therapeutic efficacy is not generally taken into consideration.

Many of you, I am sure, are familiar with the *Official Publication of the Association of American Feed Control Officials.* Each year in it there appears a list of "new drugs" and a list of "not new drugs." Certain drugs cease to be classified as new drugs when, in the opinion of experts qualified to judge safety of new drugs, sufficient experience

has been gained in their use to warrant their classification as "not new drugs," however, it must always be kept in mind that even those drugs which may be listed as not new drugs can revert to new drug status because of new recommendations, mixtures and/or levels. I think an example may help here. Phenothiazine is a well-known anthelmintic for cattle, sheep, swine, horses and poultry and under the proper labeling, adequate directions for use and warnings against misuse, this product, when mixed in commercial feed, would not be considered in new drug status. However, if a feed mixer decided to increase the recommended dose beyond that generally recognized as safe, or, let us say, he decided to recommend the medicated feed for the treatment of chronic respiratory disease in poultry or the prevention of coccidiosis in poultry, any of these would cause phenothiazine to revert to a new drug status. It would then be necessary for the feed mixer to file a new drug application with the Food and Drug Administration before the product could be legally marketed in interstate commerce.

Recent Court Decision

And since we have mentioned interstate commerce, it may be well to point out a recent decision handed down by the United States Court of Appeals for the Second Circuit, emphasizing the jurisdictional authority of the Federal Food, Drug, and Cosmetic Act over products within a given state. Briefly, the appellate court, in the *Pinnochio* case reversed the lower court's dismissal of the libel of a blend of vegetable oils, components of which had been received in interstate commerce but the blend itself had not been shipped out of state and, in this case, the state was New York state. The court of appeals held that section 304(a) of the Federal Food, Drug, and Cosmetic Act authorizes the United States to proceed against and seize misbranded or adulterated products mixed entirely within the state when the components had moved in interstate commerce. This is the most recent of a number of such cases pointing out the authority of the federal act over products that are adulterated or misbranded while held for sale, whether or not the first sale after shipment in interstate commerce. As you can see, if a drug is mixed in a feed after it has been shipped in interstate commerce even though the feed does not move out of the state, it is still subject to all the provisions of the Federal Food, Drug, and Cosmetic Act. Therefore, feed mixers are responsible for compliance with the act even though they do not have occasion to ship their feed out of the state in which it is mixed.

Another section of the law, which has had a profound impact on the manufactured feeds, is that which deals specifically with the class of products which are generally referred to as "certifiable antibiotics." These provisions of the law and the regulations issued under them determine what must be done in order to market a product that is in full compliance with the federal law. Regulations covering medicated feeds containing the certifiable antibiotics (chlortetracycline, penicillin, streptomycin, dihydrostreptomycin, bacitracin and chloramphenicol) are for the most part summed up in regulations 146.26. This regulation comprises about 30 to 40 pages and is probably the legal basis for the present day marketing of approximately 75 per cent of all medicated feeds. Briefly these regulations provide for the use of the certifiable antibiotics in medicated feeds by themselves or in combination with other drugs. Feeds covered under these regulations and not in violation of the law, must conform with these regulations which define the tag claims, feeding directions and potency —and in some cases contain the requirements of the new drug provisions of the law when a new drug is being used with a certifiable antibiotic in the same feed. The so-called antibiotic form 10 is nothing more than a modified new drug application with the added requirement to demonstrate the feed containing the antibiotic will be effective for the labeled claims.

In regard to the certifiable antibiotics and their use in animal feeds, a few changes have come into the picture during the past year. The term "antibiotic feed supplement" is no longer acceptable on animal feeds as a designation for low level of antibiotics. The specific antibiotic must be mentioned by its common or usual name and, where no therapeutic claim is made for the antibiotic, it should appear on the label under the "guarantee analysis." If therapeutic claims are made for an antibiotic, the antibiotic should be listed among the active drug ingredients, irrespective of the amount present and under these conditions the feed would be designated as "medicated." Because of some of the problems involved in the use of antibiotics in animal feeds, a general regulation was recently published in the *Federal Register* which should help answer some of the questions regarding what should be submitted to the Food and Drug Administration when a certifiable antibiotic is used in animal feed, and who should submit it.

It has been concluded that the regulations dealing with use of antibiotic drugs in medicated animal feed should be amended to make it clear that, depending upon the facts in any specific case, one of two procedures will apply. In some cases, it is possible for the scientific

evidence to demonstrate that compliance with a permit issued by the Commissioner to a drug manufacturer will suffice and that those who use the drug in mixing the feeds need do no more than follow the directions. In other cases, however, safety of the finished feed will require the operator of each mixing establishment using the drug to obtain a permit setting forth the conditions with which he must comply. The considerations here are the same as are involved in determining whether a new-drug application must be obtained by the operator of a mixing establishment who is adding a new drug substance to his production.[1]

Recently in connection with our regulatory work on medicated feeds we had occasion to follow up a complaint regarding the death of a number of turkeys due to a feed containing three times the declared qualtity of 4-nitrophenyl-arsonic acid. Inspection of the feed company showed a lack of proper controls to insure the accurate composition of feeds. Samples from interstate shipments disclosed serious deviation from the labeled declarations. This firm had a number of effective antibiotic form 10's for exemption from certification. These exemptions were granted on the basis of satisfactory control procedures to insure the proper composition of the products. Since our inspection showed that the firm did not have proper controls, the exemptions from certification were suspended which means that any further distribution of the feed covered by these exemptions would be in violation of the act.

In 1954 Congress passed special legislation, referred to as the Miller Amendment for pesticide chemical residues.

---

[1] Section 146.25 is amended in the following respects:

(1) The section heading is changed to read:

§ 146.25 Antibiotic drugs for use in medicated animal feed (antibiotic medicated feed premixes; antibiotic medicated feed concentrates that must be diluted with feed ingredients before they are fed).

(2) A new paragraph (c) is added, reading as follows:

(c) It contains no substance for which § 146.26 requires exemptions from certification of the medicated feeds in which it is used as an ingredient, unless prior to shipment in commerce:

(1) The manufacturer obtained a permit from the Commissioner issued under the provisions of § 146.22 authorizing shipment for manufacturing use to such establishment, or

(2) The operator of the establishment where such drug is to be mixed or diluted meets all the conditions for exemption from certification of the medicated feed established by the applicable provisions of § 146.26, including when required, the submission to, and acceptance by the Commissioner of adequate information of the kind required by § 146.7, to establish the safety and efficacy of the finished medicated feed and to guarantee its identity, strength, quality, and purity.

Legal Tolerance

Persons who wish to promote a pesticide chemical must first secure evidence about its toxicity to animals, the amount required for the particular purpose and the amount that will remain on the food after its use. These facts are submitted along with others to the Food and Drug Administration with a request to set a formal tolerance for safe residues of the chemical on a specific raw agricultural product. Simultaneously the United States Department of Agriculture is asked to certify that the chemical is useful. When the Food and Drug Administration has the certificate of usefulness, it determines what amount of the chemical may be consumed daily for the lifetime without any harm. Using all this data, a safe legal tolerance is set as the level to be permitted. No amount of the particular chemical may be permitted in excess of that which meets the need of agriculture. If the chemical is too toxic to remain on food in any amount, the tolerance is set at zero. If the chemical is relatively harmless so that any foreseeable use of it will not be a hazard to the public health, it may be exempt from the requirements of a tolerance.

When a tolerance is set for a pesticide chemical this means that: (1) crops in interstate commerce should bear no more than the tolerance level of residue, (2) residues within the tolerance are safe, (3) the chemical is useful and (4) when used properly the chemical will not leave residues above the safe level.

The Food and Drug Administration will not establish a tolerance for a toxic compound in or on forage if the feeding of this forage leaves residues in animal tissues unless the petitioner has presented evidence to show that the residues in milk, eggs and meat are safe, and the Food and Drug Administration simultaneously grants tolerances for the residues in the by-products. Tolerances for pesticidal residues apply only to the raw agricultural products. It is our obligation to see that established tolerances are observed and that unauthorized residues are not present.

A point of interest is the effect, if any, of processing upon the pesticidal level in a processed article, for example, a commercial animal feed. The concentration of pesticide cannot exceed that which is permitted on the raw product unless authorized by the Food Additives Amendment.

In March, 1959, the provisions of the Food Additives Amendment to the federal law, enacted in September, 1958, became operative,

except for products that had been in commercial production prior to January, 1958.

Food Additives Amendment

Substances covered by the Food Additives Amendment are those additives not generally recognized by competent experts as having been adequately shown to be safe under the conditions of their intended use. The amendment covers substances that are added intentionally to food as well as those that may reasonably be expected to become a component of food. Substances used in food or feeds that are generally recognized as safe because of experience based on such use or which have been established as safe through scientific procedures are exempt from the provisions of the amendment. Also exempt are substances that have had prior approval by the government for use in foods or feeds under the Federal Food, Drug, and Cosmetic Act, the Meat Inspection Act and Poultry Products Inspection Act. Briefly the new amendment makes the following requirements with the respect to additives:

(1) The available data must establish that the proposed use of the additive under the conditions to be specified in the regulation will be safe.

(2) No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.

(3) The additive must not, under the proposed conditions of use, promote deception or othewise cause a food to become misbranded or adulterated under any provisions of the Act.

(4) Where it is necessary to affix a tolerance limitation in order to assure that the proposed use is safe, the tolerance set must not be greater than for the amount necessary to achieve the intended physical or other technical effect and none will be permitted if the proposed use fails to accomplish this effect.

(5) A practical assay method must be available for checking residues of the chemical or drug.

Some wonder whether the anticancer clause of the Food Additives Amendment is a reasonable requirement. There is no need to repeat the arguments on both sides of this question.

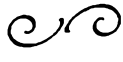
As most of you know, we believe that there is no valid basis for considering a change in the basic principle of the anticancer clause until science makes a breakthrough in this area.

On the other hand, there is no public health reason for having the anticancer clause apply to a product for use in animal feed where use of the chemical does not harm the animal and leaves no residue in food derived from the treated animals.

Under the law, any substance to be added to animal feed that is not itself generally recognized as safe must be shown to be safe for the animal under the intended conditions of use. Where this cannot be demonstrated, authorization to use the additive will be denied forthwith. Where safety to the animal can be established, then the petitioner must demonstrate either that the edible products of the animal—meat, milk, or eggs—are free of any residues of the substance and its degradation products, or where such residues are found, that they will be safe for consumption by man or other animals, as the case may be. That, in a nutshell, is the requirement the Food Additives Amendment imposes on animal feed.

In summary, the Food, Drug, and Cosmetic Act is a consumer protection law. It forbids interstate commerce in adulterated or misbranded foods, drugs, devices and cosmetics. Medicated animal feeds are subject to the same provisions of the law as are the foods and drugs for humans. Specifically these include the new drug provisions, the certifiable antibiotics provisions, the pesticide chemical amendment of the act and the most recent, the food additive provisions of the law.

All of us who are interested in livestock production must primarily be concerned with the question of whether the food for man obtained from treated animals can possibly have any adverse effect on the human consumer. If there are any questions of safety to be resolved, they must be always resolved in favor of public health protection. **[The End]**



Operations of the Food and Drug Administration

By GEORGE P. LARRICK

Mr. Larrick Is Commissioner of Food and Drugs of the Department of Health, Education and Welfare. This Paper Was Presented Before the Medical Advisory Committee Session Held in Conjunction With the 41st Annual Meeting of the American Petroleum Institute in Chicago, Illinois on November 13, 1961.

THE FEDERAL HAZARDOUS SUBSTANCES labeling act creates new areas of common interest for us. The problems involved in waxes for food containers and mineral oil used in a variety of ways in the food, drug, and cosmetic industries are examples of our mutual interests.

Mineral oil is a drug, which, when properly labeled to advise against ingestion with meals and with other labeling precautions, may be distributed for medical purposes. When it gets into the food supply as salad oil it is illegal, since, as you know, it interferes with the absorption of fat soluble vitamins.

The research being carried out by your industry and the coordination of available resources will, we hope, resolve these and other problems.

The Food and Drug Administration is a part of the Department of Health, Education, and Welfare. Our responsibilities include the enforcement of the Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substances Labeling Act. We have over 2,200 employees, of which two-thirds are stationed in 18 district offices and 40 inspection stations in principal cities throughout the country.

Our Washington office includes administrative, research, and technical units. In enforcing these acts, our inspectors make periodic investigations of establishments where products subject to the laws are manufactured, held, or sold, to determine their compliance with the law. They collect samples from interstate shipments, and our

scientists examine the samples to determine whether the shipments are legal.

Both laws provide for seizure through the federal courts of illegal products to remove them from the market. Persons responsible for introducing such products into commerce may be prosecuted. Injunctions may be obtained to restrain individuals and firms from further violation of these laws.

We review evidence submitted as to the safety of new drugs before they are placed on the market, and determine the safety of color additives used in foods, drugs, and cosmetics. Batches of insulin and five of the most important antibiotic drugs and their derivatives are checked for purity and potency before they are sold. The law provides for the establishment of the amount of pesticide residues that may safely remain on food. Regulations are issued stating safe conditions for using food additives. Imports are examined to determine that they meet the requirements of the United States laws.

Our basic philosophy is to employ preventive measures rather than punitive enforcement but where necessary we vigorously pursue enforcement in the courts.

The Federal Hazardous Substances Labeling Act gave us new responsibilities. Before its passage we enforced the Federal Caustic Poison Act. That law was passed after the medical profession, under the urging of Dr. Chevalier Jackson of Philadelphia, became alarmed at the increasing number of children who were injured from swallowing household lye and other caustic poisons. The statute was narrow in scope when considered in the light of today's mode of living. It covered a small group of highly caustic agents, requiring the word "poison" and certain other information on labels.

Within a few years after this act became law, health authorities recognized that it did not cover many hazardous household products that were coming on the market in volume. Developments brought about by research during and following World War II accelerated the introduction of more chemicals as household aids. Many of these products were labeled to advise against misuse. Others, though toxic, were not adequately labeled. Injuries from them increased. Their containers frequently gave the physician no information to assist in treating the injuries, and delay in treatment did lead to serious consequences. All of this led to the establishment of the poison control centers with which you are familiar. Through the American Medical

Association, physicians called for better controls to reduce the injuries and deaths resulting from accidental ingestion or other misuse of these products.

The Food and Drug Administration and many responsible officials of chemical and manufacturing firms supported a stronger and more comprehensive law.

Aspects of the New Act

Congress recognized this need and on July 12, 1960, the Federal Hazardous Substances Labeling Act became law. It requires hazardous household articles to bear labeling to warn users, and parents of inquisitive youngsters, of the dangers of these products.

This Act requires that warning labeling be placed on containers of products which meet two tests: (1) if it is a "hazardous substance" which may cause substantial personal injury or substantial illness as a result of any customary or foreseeable handling, and (2) if it is a container intended or suitable for household use. The Act defines a hazardous substance as one that is toxic, corrosive, an irritant, a strong sensitizer, flammable, or pressure generating. If it meets any of these definitions, certain labeling is required. The labeling must bear conspicuously the common or the chemical names of the hazardous substance; the signal word "danger" on all substances which are extremely flammable, corrosive, or highly toxic; the word "warning" or "caution" on all other hazardous substances; a statement of the principal hazard or hazards; precautions to be followed; the word "poison" for highly toxic substances; when necessary, special instructions for handling and storage; instructions where needed for first aid treatment; and the statement "keep out of the reach of children" or its equivalent. The name and place of business of the manufacturer, packer or seller must also be shown.

Congress provided certain tests to determine if a product is hazardous, and animal tests to ascertain if a substance is "highly toxic." The law also recognized that empirical tests are not always reliable as criteria for a product's potential for harm. Therefore the act specifies that human experience is to be the controlling factor, regardless of a product's theoretical potential for harm. If a substance does not cause harm as ordinarily used, and if accidental harm is not reasonably foreseeable, it is not a hazardous substance. Conversely, if it may cause harm under reasonably foreseeable use, it is a hazardous substance.

Congress also included two other very important concepts in this law. If the Secretary of Health, Education, and Welfare finds that the minimum labeling requirements are not adequate for the protection of the public health in view of some special hazard, he may establish reasonable variations or additional label requirements necessary for this protection. If because of the size of the package involved, or because of the minor hazard presented by the substance, the Secretary concludes that full compliance is not necessary, he may exempt containers of hazardous substances from all or part of the required labeling. The test is whether such exemption can be made with no harm to the pubilc health and safety.

It was necessary for us to implement many provisions of the act by regulations. Some definitions required clarification. Methods for testing the products were needed. Industry sought our views on the labeling of hazardous substances.

The Food and Drug Administration convened two separate panels of medical experts to help resolve these complex problems. One panel included some of the country's outstanding experts on dermal toxicology; and the other included equally outstanding experts on pharmacology and clinical toxicology. These scientists had a real interest in the public health and practical aspects of labeling requirements on hazardous substances found around the household. Some were leading participants in the management of poison control centers.

Rule's Application to Petroleum Industry

The provisions in our regulations of most interest to the petroleum industry were developed on the basis of recommendations of these committees. For example, the section dealing with "products requiring special labeling" lists substances known to be hazardous because they frequently cause injuries. Among these are petroleum distillates and mixtures containing 10 per cent or more of such distillates. The labeling required for petroleum distillates (and turpentine) is: the signal word "danger"; the additional statement "harmful or fatal if swallowed"; and for kerosene and related petroleum distillates, the warning "do not induce vomiting."

These provisions were recommended by the panel of experts largely because of the pulmonary complications caused when petroleum products are aspirated into the lungs. The Public Health Service reports pulmonary complications in almost 50 per cent of the cases involving the ingestion of kerosene or certain related chemicals.

We understand some industry representatives have evidence which convinces them that certain products containing 10 per cent or more of petroleum distillates are not hazardous. If you have such evidence mail it or bring it in, and let's discuss it.

There are areas where the new regulations can be improved. Your assistance will be of value to the Food and Drug Administration and to the public as we undertake the administration of this law.

An education program will be required to get the various firms and dealers who repack hazardous susbtances to do it properly. For example, hazardous substances such as kerosene and gasoline poured into small containers must be appropriately labeled. In the past, little or no labeling has been applied to them. There have been many instances, as you know, of serious injuries and deaths in the home from mishandling such products. The new law requires that informative labeling be carried through, not only on the merchandise as it crosses a state line in household size packages, but also on the merchandise that is repacked into small containers after it crosses a state line. Service station operators and others will need to be advised how they can meet the requirements of the law. Your Institute and other responsible industry groups will be of great assistance in helping to present to all who are affected, a clear, concise story of the methods to be followed.

The Hazardous Substances Labeling Act is a law in the public interest. We invite your suggestions for improvement in the regulations and our administration of the statute. **[The End]**

CHAIRMAN DIXON TO PARTICIPATE IN DRUG COMPANY CASE

Federal Trade Commission Chairman Dixon told six drug companies that he would participate in the commission's review of a hearing examiner's ruling dismissing charges that the companies fixed prices and misused a patent. The companies had asked the chairman to disqualify himself in view of his prior position and duties as counsel and staff director of the Senate Subcommittee on Antitrust and Monopoly during its investigation of pricing and other practices of the ethical drug industry. Also, the commission refused to reconsider a prior ruling turning down a disqualification motion directed to the agency.—TRADE REGULATION REPORTS—*American Cyanamid Company* ¶ 15,727.

FDA Role in the Labeling of Blood Bank Products

By EARL L. MEYERS

Mr. Meyers Is the Chief Chemist in the Division of New Drugs of the Bureau of Medicine, Food and Drug Administration, Department of Health, Education and Welfare. He Presented This Paper at the Annual Meeting of the American Association of Blood Banks on October 27, 1961, in Chicago, Illinois.

I SINCERELY APPRECIATE THIS OPPORTUNITY to appear before you this morning and to have the privilege of taking part in your program as well as talking with you individually. We welcome opportunities such as this because we believe they are productive of a greater understanding of our joint problems. We know that you are vitally interested in the protection of the public health, and that we have your cooperation and active help in dealing with the public health problems in the blood banks field. Your association has carried on a number of activities that promote our common goals.

For those of you not familiar with the Food and Drug Administration, I would like to describe briefly some of its functions and organization. The Food and Drug Administration enforces the Federal Food, Drug, and Cosmetic Act, designed among other things to regulate traffic in drugs that move from one state to another. This statute prohibits interstate commerce in adulterated and misbranded drugs and new drugs until their safety has been established.

We are an organization made up primarily of scientists—physicians, pharmacologists, chemists, bacteriologists, pharmacists and other scientists needed to administer intelligently a law which is designed to insure that drugs have the quality and properties claimed for them.

Perhaps I should tell you just where we are in the governmental picture. This administration is one of the health agencies in the United States Department of Health, Education, and Welfare. The Public Health

Service with its Division of Biologics Standards of the National Institutes of Health is one of our sister agencies in the department.

To carry out our regulatory functions, we have 18 field district offices in the major cities throughout the United States. Each is staffed with a group of inspectors who make field investigations and each has a laboratory where most regular analyses can be made. In addition to this field organization, we have a headquarters staff in Washington for planning and supervision and a Bureau of Medicine to furnish advice on medical questions. We also have in Washington certain specialized laboratories which are staffed and equipped to conduct research and to do specialized laboratory analyses.

I think it would be well to tell you some of the things that we do not do, because that is a source of some confusion and misunderstanding. The regulation of advertising is primarily a function of the Federal Trade Commission and not of the Food and Drug Administration. The strict controls exercised over the distribution of narcotics is a function of the Bureau of Narcotics of the Treasury Department. Finally, the Division of Biologics Standards of the Public Health Service licenses the manufacture and interstate distribution of serums, toxins, vaccines and similar products, including human blood and its derivatives. We do virtually nothing in the way of regulating the quality or use of products subject to this special law except on the occasions when we are requested to do so as assistance to the Public Health Service. However, the Food, Drug, and Cosmetic Act and the regulations based on it, as well as the Public Health Service Act apply to biologicals. In the application of the laws, the Public Health Service operates with exclusive jurisdiction with respect to biologicals except to the extent they choose to enlist the cooperation of the Food and Drug Administration. In these circumstances, it is reasonable for the Public Health Service to enforce the same principles of labeling for biologicals as are applicable to other pharmaceuticals.

History of These Laws

We might briefly outline the history of these laws and the provisions on which I base the statement that both laws apply to biologicals. Federal regulation of biologicals preceded the regulation of other drugs. The Federal Virus, Serum, and Toxin Act was enacted in 1902 and was later incorporated in the Public Health Service Act of 1944. The first federal regulation of drugs other than biologicals was contained in the Food and Drugs Act of 1906, which was super-

seded by the Federal Food, Drug, and Cosmetic Act of 1938. Section 902(c) of the Food, Drug, and Cosmetic Act provides that nothing contained in the Act shall be construed as in any way affecting, modifying, repealing, or superseding the biologics law. Similarly, Section 351(g) of the Public Health Service Act provides that it shall not be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act. Finally, we should note that the term "drug" in the Food, Drug, and Cosmetic Act is defined so broadly as to include biologicals (Section 201(a)).

For many years the Public Health Service has quietly taken into account the requirements of the Food, Drug, and Cosmetic Act, and regulations thereunder in its administration of the federal laws applicable to biologicals. It is evident that any amendment of the Food, Drug, and Cosmetic Act and regulations necessarily affects the regulation of biologicals. We are particularly concerned today with certain profound changes in the regulations affecting the labeling of prescription drugs, that were promulgated during the past year.

Among the labeling requirements in these regulations, as revised (Subparagraph 1.106(b)(2)), the label of the prescription drug must bear the prescription legend, recommended or usual dosage and the route of administration if not for oral use. The quantity or proportion of each active ingredient must also be included as well as information required by the Act in regard to habit-forming drugs and certain others, an identifying lot or control number, if it is for other than oral use the names of all inactive ingredients, and if it is for injection, the quantity or proportion of all inactive ingredients.

An exemption from the requirement that this information appear on the label is allowed only because of insufficient label space. Note that there is no exception concerning the quantity or proportion of each active ingredient and the lot or control number, except use of the crimp in dispensing tubes, because of insufficient label space. Note also that if the retail unit of the drug is packaged with an outer carton or wrapper, information required to appear on the label must also appear on the carton or wrapper unless the label is easily legible through it.

You will recognize that most of these regulations have been in effect for years. The significant changes are the requirements that the labeling of drugs for parenteral administration bear a complete quanti-

tative statement of composition, including inactive as well as active ingredients, and that the label must bear a lot or control number from which it is possible to determine the complete manufacturing history of the package.

There are several exceptions to these label requirements other than insufficient label space. In regard to stating the quantity or proportion of inactive ingredients in injections, water for injection need not be named if it is the vehicle and ingredients added in small amounts to adjust to a specified pH or to make the drug isotonic may be named with a statement of their effect. With respect to the usual or recommended dosage, no package insert is required solely because the label bears this dosage information.

The most sweeping labeling changes contained in the revised regulations require that the package from which the drug is dispensed must include adequate information for its professional use, (1.106(b)(3)). The only exemption is the case of a drug whose uses are commonly known to practitioners. This exemption is construed very narrowly. For example, all drugs for parenteral administration require such information in the package. This so-called package insert requirement will become effective in March, 1962. In practice, this requirement has applied to parenterals for quite some time.

"Full Disclosure" Requirement

Closely related to the package insert requirement is a general provision (1.106(b)(4)) already in effect, that any labeling for prescription drugs, whether or not it is part of the package, that furnishes or purports to furnish information for use of the drug, must contain adequate information for such use. Adequate information as applied to labeling that may be mailed or detailed to physicians or that used as a package insert includes indications, effects, dosages, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended. This has become commonly known as the "full disclosure" requirement. Further, the regulation requires that the labeling, (1.106(b)(5)), bearing such information for use must bear the date of its issuance or its latest revision.

The full disclosure concept has a two-fold purpose. One is to make full information for the maximum safety and efficacy in the use

of prescription products readily available to the medical professions, and the other is to eliminate the use of labeling for prescription products that is misleading by reason of the omission of information concerning the hazards and limitations of the product while extolling its virtues.

You may be interested in the background of the development of these revised drug labeling regulations. Before a new drug may be marketed the act requires a manufacturer to submit an application demonstrating that the drug is safe for use as recommended in his proposed labeling. The information in the labeling is critical to safety in the use of potent new pharmaceuticals. However, the only assurance that this critical information would reach physicians was the statement on the label of the new drug to the effect: "literature available to physicians on request." Our experience showed that this basic information on the uses, hazards and contraindications was not, in fact, being made available to the medical profession. Too frequently, manufacturers disseminated a mass of unsolicited promotional literature to physicians detailing the claimed advantages of the drug but omitting information concerning its hazards. Generally, physicians did not request or receive the complete information needed for maximum safety and efficacy in use of the drug.

The abandonment of the philosophy that a statement on the label of a drug, "literature available on request," satisfies the labeling requirements of the act could not reasonably be limited to new drugs. The rate of introduction of new drugs had greatly exceeded the capacity of physicians to keep informed of the proper uses of the great number of available pharmaceuticals. It was the consensus of our medical staff that adequate information for professional use of most prescription drugs was not readily available and that there was a real need to make such information readily available.

Consequently, in July, 1960, we proposed regulations to revise the labeling requirements of prescription drugs. In view of the changes in the pattern of labeling prescription drugs that would be required by these regulations, we published the revisions as proposals with opportunity for comment by interested persons.

We received a large volume of comments and held a number of conferences on the proposed regulations. Virtually all of the written comment endorsed the principles that the labeling of prescription

drugs should be informative and should not mislead. Some pharmaceutical manufacturers and trade associations were critical of specific provisions in the regulations. A number of strong endorsements of the proposed regulations were received from public health officials, individual physicians, pharmacists and scientific associations.

Based on careful evaluation of all of the comments received on the proposed regulations, modifications were made in some instances from the original proposals. For example, we adopted a trade recommendation to allow the lot or control number of a drug to be stamped on the crimp of a collapsible tube. The proposal to require quantitative label declaration of the inactive ingredients of drugs for ophthalmic use was modified to require only the naming of such ingredients, since this would provide sufficient information for physicians to avoid use of an article to which a patient is known to be sensitive. On the other hand, the requirement that inactive ingredients of drugs for administration by parenteral injection be disclosed quantitatively on the labels was retained despite manufacturers' objections. Such information has been required for years in the labeling of injections official in the *United States Pharmacopeia* or *National Formulary* and the considerations of safety underlying these requirements for official injections are equally applicable to all injections.

Final regulations were published in December, 1960, and January, 1961, with respect to all provisions of the proposed regulations except a proposal for the so-called package inserts to provide full information about the drugs. In September, 1961, we issued, in final form, a regulation requiring each prescription drug (except those whose uses and contraindications are commonly known to doctors) to bear a package insert giving full directions and warnings.

We believe these changes will result in a vast improvement in the quality of information going to physicians.

This discussion has presented the basis for the application of the Food, Drug and Cosmetic Act to biologicals and an introduction to the major concepts contained in the revisions in labeling regulations adopted during the past year. In practice, manufacturers of biologicals will work out the labeling problems related to the revised regulations in their relationships with the Public Health Service, Division of Biologics Standards. Although this discussion could not possibly cover all of the questions, I will try to answer any additional questions of special concern you may have. **[The End]**

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

December Drug and Device Seizures.—Twenty-nine federal court actions were instituted against devices charged to be adulterated and misbranded.

Typical of products involved in the seizures on charges of false and misleading label claims were:

Bio-Tan Tablets, claimed to have a tanning effect; Hesperidin & C Tablets and Hesprin A-C Tablets, claiming to relieve rheumatism and prevent abortion.

Zinsep Compound Antacid, promoted as "finest ulcer-healing medication" and "America's greatest stomach remedy."

Prescription Number H-525, for control and prevention of rhinitis in hogs.

Super Health Magnetic Bracelet, a device claimed to relieve arthritis, rheumatism, high and low blood pressure and sexual impotency.

Juicex Device, claiming to be effective in treatment of bladder tumors, leukemia, cancer, angina pectoris, impotence, epilepsy, meningitis and brain tumors.

Other seizures involved repackaged physician's samples, vitamins, drugs and prophylactics differing in potency or quality from label claims or official standards and a facial cream labeled "Federal Pure Food and Drug Administration Seal of Approval." The Food and Drug Administration does not have a "Seal of Approval."

Food Seizures.—Approximately 758 tons of food were seized in 60 actions on charges of contamination.

Among the foods seized to protect consumer health were 53 tons of soy beans, containing poisonous crotalaria seeds, and 24 tons of dehydrated alfalfa meal containing a nonpermitted residue of DDT.

Another seizure in this category was a shipment by the Preston-National Drug Company, Dallas, Texas, of 6,900 capsules of Hematonic Formula and High Potency B. Complex, containing folic acid in excess of that permitted in products for sale without perscription.

The largest seizures of filthy and spoiled foods involved 161 tons of rodent-contaminated popcorn, 141 tons of wheat, also 120 tons of rodent-contaminanted, insect-infested vitamin-and mineral-fortified rice, and 15,538 gallons of various California wines, produced and held under insanitary conditions.

More than 50 tons of rancid and moldy nuts, filthy flour, decomposed eggs, shrimps, pineapple preserves (13 tons), and approximately 20 tons of tomato paste, prepared and packaged under insanitary conditions, were included in the foods seized on charges that they were unfit for human consumption.

Labeling violations and charges of quality below official standards were responsible for 15 seizures totaling 324 tons of food.

The target for these kinds of violations is always the consumer's pocketbook, but the form varies, as few examples of December seizures will show:

More than 1,300 cases of 12 ounce cans of frozen orange juice concentrate, labeled as "can equals juice of 24 average size, tree-ripened oranges," a statement alleged to be false and misleading; egg noodles, below standard because they contained no egg yolks; "paprika," containing added salt and artificial coloring; and apricots, packed in sweetened water instead of sirup as labeled.

Twenty-six tons of Vienna sausages were seized in Puerto Rico on charges that cereal and water were substituted for part of the meat.

Thirty tons of freestone peaches containing fruit of excessive hardness, and ten tons of canned tomatoes containing excessive peel were seized on charges that they were below official quality standards.

Voluntary Actions by Industry.—According to December reports, 127 actions were taken in which 1,700 tons of violative food were destroyed or converted to feed, and $333,439 worth of drugs were withdrawn from the market by industry to avoid traffic in violative products.

A brewing company in Pennsylvania voluntarily dumpted 266 tons of insect-infested corn frits for use in the manufacturing of beer, and 7,700 barrels of the beer that had already been made from infested grits. It added an anti-foaming agent to the beer and dumped it down the city sewers, under the supervision of an inspector from the Buffalo District.

A peanut company in Texas spent $200,000 on the construction of concrete silos for more sanitary storage of farmer stock nuts.

Rodent infestation found in a Nebraska corn meal mill prompted the plant management to convert 19,000 bushels of corn into animal feed.

A dairy company in Nebraska installed humidity controls and air-conditioning in its warehouse. It also built a new plant with an automatic system providing for scheduled milk-bottling, mixing, and cleaning, raising its operations to high sanitary standards. The cost of this improvement was $1,125,000.

FDA in 1961.—At the end of 1961 Food and Drug Administration had completed one of its busiest years. Here are the final tabulations.

More than 36,000 inspections were made of food, drug and cosmetic establishments during the year, compared with 26,300 during calendar year 1960.

Inspectors collected over 67,000 samples and FDA chemists analyzed over 46,000 samples to determine their compliance with the Federal Food, Drug and Cosmetic Act. Comparable figures for 1960 were 45,900 and 40,700.

Foods seized in 658 federal court actions totaled more than 9,100 tons down slightly from 696 actions and 10,400 tons in 1960.

But the food and drug industries of the country also played an important part in protecting the public from unfit products. Over 20,000 tons of deteriorated or contaminated food commodities and products were voluntarily destroyed or converted to animal feed in over 1,100 such actions witnessed by FDA inspectors. Adulterated drugs originally worth $1,573,000 were disposed of in 393 individual actions. And FDA inspectors reported a total of 237 plant improvements to prevent future violations of the law, at a cost of $8,986,000, up from $6,700,000 last year.

Criminal prosecution filed in the federal courts in 1961 totaled 309. Of these 120 involved adulterated or misbranded foods; 189 were concerned with defective or dangerous drugs without prescription.

2 *Brand-New Tax Helps From CCH*

1. EXPENSE ACCOUNTS—1962—Both employers and employees will welcome this handy booklet as a guide to reporting and record-keeping requirements under today's expense account rules. Among some of the many helpful features are a complete explanation of federal expense account tax rules, a section on travel and education expenses, solutions for tax return problems, and sample records and forms for sound expense account management, plus quick reference check lists of deductible and nondeductible expenses. You'll also get an advance, inside look at hot new legislation covering expense accounts scheduled for early action in Congress. Topical index; 48 pages. 6″ x 9″, heavy paper covers. Price, $1.

2. NEW PROFESSIONAL CORPORATION LAWS EXPLAINED—Federal Tax Savings—Retirement Benefits—State Taxes—Fees—The door is now open to professional people in many states to adopt plans eligible for the same favorable tax treatment the Internal Revenue Code gives other employee retirement plans. However, to get this same treatment, these professional people must either incorporate or form professional associations under their state's laws before they may establish any kind of qualified deferred compensation plan. Here, packed into 96 informative, easy-to-understand pages, is a complete explanation of the federal tax situation; full texts of the state association and corporation laws; and a listing of the state tax rates, fees and report requirements that apply. Also included is a helpful discussion for each state, in terms of its statute, of the four IRS tests for corporate characteristics. The whole story, all the facts about this unusual and important tax-saving plan are yours in a nutshell with this brand-new CCH booklet that tells what you must know and do. Topically indexed, heavy paper covers, 6″ x 9″. Now ready for delivery! Price, $2.

Order Your Copies Now on this Handy Tear-off Card! ➡

DEPENDABLE—COMMERCE CLEARING HOUSE PUBLICATIONS

CCH PRODUCTS COMPANY

BOOKS BY MAIL

4025 W. PETERSON AVENUE, CHICAGO 46, ILLINOIS

A COMMERCE CLEARING HOUSE PUBLICATION

BUSINESS REPLY MAIL

NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY—

CCH PRODUCTS COMPANY

4025 W. PETERSON AVE.

CHICAGO 46, ILL.

ORDER CARD

DETACH AND MAIL TODAY!

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.

ORDER CARD

Send for These Handy Tax Helps Today

CCH PRODUCTS COMPANY
4025 W. Peterson Ave.
Chicago 46, Ill.

Enter our order for the quantities of CCH books indicated at prices quoted. (Remittance with order saves postage and packing charge.)

Fill in Amt.

1. .... Expense Accounts—1962 (2118). Prices: 1 to 4 copies, $1 ea.; 5-9 copies, $.90 ea.; 10-24, $.80 ea.; 25-49, $.70 ea.; 50-99, $.57 ea.

2. .... New Professional Corporation Laws Explained (2120). Prices: 1 to 4 copies, $2 ea.; 5-9, $1.75 ea.; 10-24, $1.50 ea.; 25-49, $1.25 ea.; 50-99, $1 ea.

☐ Remittance herewith ☐ Bill us

☐ Quote prices on larger quantities with our imprint—for items circled: 1 2

Signature & Title .....

Firm .....

Attention .....

Street Address .....

2118—182

City, Zone & State .....

(Subscribers for CCH's Standard Federal Tax Reports receive items 1 & 2; Federal Tax Guide Reports and Federal Tax Guide Reports—Control Edition receive item 1; Corporation Law Guide and Pension Plan Guide receive item 2; and Current Law Handybooks receive items 1 & 2. They should order only for extra copies.)