VOL. 19, NO. 6 JUNE 1964

Food Drug Cosmetic Law JOURNAL

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: 1 year, $20; 3 years, $49; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

June, 1964
Volume 19 • Number 6

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . June, 1964

VOLUME 19 NUMBER 6

Printed in the United States of America

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Medical Research.—The president of the Pharmaceutical Manufacturers Association, *Austin Smith, M. D.,* discusses "Medical Research by Law and Regulation," in a paper which begins on page 317. "It may well prove to be that through research in the medical field, which is an ever-increasing necessity, there will emerge the kind of voluntary, cooperative, self-policing leadership that will lessen the demand for regulations and legislation. It is conceivable, too, that those in the health field who have recently been sharing the spotlight of public attention may in time be able to spend more time on creating progress and less on repair of damages," he concludes.

International Food Standards. — In his article, "A New Vital Influence in International Food Standards," the author makes a general observation of basic importance to the effect that a food standard, when appropriately supported and backstopped by practical standards for sampling, analysis and other requisites, should aim at ensuring the market of a sound, wholesome product, correctly labeled and presented. "It should not be intended to affect consumer preference, but should aim at ensuring that the consumer can know what he is buying," the author, *Nathan Koenig,* states. Mr. Koenig is chairman of the United States Food and Agriculture Organization Interagency Subcommittee on Codex Alimentarius and Special Assistant to the Administrator, Agricultural Marketing Service, United States Department of Agriculture, Washington, D. C. His comments appear at page 326.

Complying with Food Laws.—*Franklin M. Depew,* Food Law Institute president, advises industry to "cooperate as fully with the FDA in a factory inspection in furthering the remedial purposes of the law as the circumstances permit." In an article appearing at page 337, he comments on FDA's request for expanded factory inspection authority and explains why both industry management and industry lawyers are opposed to this proposal.

Dissimilar Objectives?—The author is of the opinion that the fundamental objectives of government and industry in the food and drug areas are by no means poles apart. "Every government official is a consumer. He wants his foods and drugs to be safe and effective; he does not want to pay excessive prices for them . . . he does not wish effective drugs to be kept off the market. . . . those in industry are also consumers and do not wish to depopulate the country by the manufacture of lethal drugs." This article, "Government and Industry—Are Their Objectives Dissimilar?" by *Vincent A. Kleinfeld,* a member of Bernstein, Kleinfeld & Alper, in Washington, D. C., begins on page 345.

Our Food Is Very Safe.—This is the opinion of *Robert S. Roe,* director

of the Bureau of Scientific Standards and Evaluation of the Food and Drug Administration. In an article appearing on page 351, Mr. Roe concludes that "the complexity of our present-day civilization, the continued advances in science and technological applications in agriculture and industry make it more essential than ever that up-to-date, well-designed and adequately enforced regulatory laws continue with respect to foods and drugs. Our food supply will continue to be safe so long as producers, manufacturers, distributors and government regulatory agencies remain alert and maintain sound scientific controls."

Scientists' Forum.—The JOURNAL'S Scientific Editor, *Bernard L. Oser,* tells of the progress of the Food Chemicals Codex in a report which appears at page 357. The project is sponsored by the Food Protection Committee of the National Academy of Sciences-National Research Council. Dr. Oser is president and director of the Food and Drug Research Laboratories, Inc.

ABA Meeting.—The American Bar Association Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law will meet on August 12, 1964, in New York City, according to Division Chairman, *Franklin M. Depew.*

A member of the Washington, D. C. firm of Markel & Hill, *Bruce J. Brennan,* will open the talks with a discussion of "Affirmative Disclosure in Advertising and Control of Packaging Design Under the Federal Trade Commission Act." *William W. Goodrich* will comment on "The Coming Struggle Over Vitamin-Mineral Pills." Mr. Goodrich is Assistant General Counsel, Food and Drug Division, Department of Health, Education and Welfare.

A panel of prominent men in the field will discuss products liability problems. *William J. Condon,* Counsel for Swift & Company, New York, will serve as moderater. The other panelists will be: *Richard W. Duesenberg,* counsel, Monsanto Company, St. Louis, Missouri; *Arnold B. Elkind,* Zalenko and Elkind, New York; *Warren Freedman,* staff counsel, Bristol Meyers Company, New York; and *Frederick A. Hart,* professor, Boston College Law School, Chester Hill, Massachusetts.

Speaker at the noon luncheon will be *John L. Harvey,* Deputy Commissioner of the Food and Drug Administration, Department of Health, Education and Welfare. His topic will be "Report on the Growth, Organization, Operations and Plans of the FDA."

The Division's business meeting will follow, featuring election of officers.

Vol. 19, No. 6 June, 1964

Food·Drug·Cosmetic Law
Journal

Medical Research by Law and Regulation

By AUSTIN SMITH, M.D.

This Address Was Presented Before the Proprietary Association in White Sulphur Springs, West Virginia, on May 11, 1964. Dr. Smith Is the President of the Pharmaceutical Manufacturers Association.

THERE HAS BEEN SO MUCH PUBLICITY recently about changes in the Federal Food, Drug and Cosmetic Act and about research regulations issued by the Food and Drug Administration that some people are beginning to assume that all leadership for medical research stems from Washington. Furthermore, so many hearings and investigations have been held in this city that others are beginning to believe that control over medical research must rest in Washington. In fact, there are researchers, administrators and others who wonder if this does not already exist because of the Washington largesse observed in the eager desire to underwrite research with public funds. And this largesse can lead to a form of regulation over project, manpower and site of the research.

The story of medical research will never be completed by public law, public regulation and public subsidy. This is a complex subject that goes far beyond the understanding of any group that is oriented to only one, or even several aspects of life. For example, the man who believes that money alone can buy answers to all research questions, or who believes that safety in research can be achieved by regulation, or who contemplates the guidance of all research through master planning by momentarily labeled experts, is either naive or devious. Research ranges from the test tube to the bedside, from the glass enclosed laboratory to the open fields, from technician to subject

specialist, from law maker to citizen, from government to private enterprise. And, in addition, research wanders from discovery of a new chemical, through control over production, past refinement in a product to render it more useful, to determination of public health needs, yes, even to public acceptance. For it is one thing to reveal a basic discovery and another to mold it to suit a health need, and sometimes still another to encourage public acceptance, or, as is sometimes necessary, to prevent public rejection. It is in such areas that understanding may be even more important than know-how. And strangely, sometimes the understanding is most urgently needed by those who make the product, by those who legislate and regulate, and by those who use it.

Wording and Objectives of Regulations on Research

The members of this audience probably are acquainted in varying degrees with the wording and objectives of the regulations issued by the FDA and the Kefauver-Harris amendments that touch on research. If not, much information is available for the asking from the headquarters office of the Proprietary Association, the Pharmaceutical Manufacturers Association, and elsewhere. In general, they reflect needs for more research and more records, and the use of more personnel in industry, academic, professional and government circles. No one can quarrel with the publicly stated objective of such changes, but many quarrelled justifiably with some of the wording and some of the interpretations placed on the wording. Furthermore, considerable regret has been expressed in responsible quarters over the fact that some legislators and regulators have been more influenced by personal beliefs and public excitement in some instances than by the yardstick of scientific knowledge. In fact, some deliberations have stretched from the halls of Congress to the courts and it seems possible, yes probable, that even more activity will be witnessed in the courts as regulation and science meet in conflict.

In this age of therapeutic plenty, the right to use new drugs has been challenged and the speed with which medical science has moved during the past three decades is threatened. Accusations, fears, indecision and regulations and legislation may retard medical research to the point where shades of an involuntary moratorium may seem at hand. It requires profound wisdom, judgment and skill to decide when and under what conditions a drug should be made available to or taken away from the physician for use in his practice. Although

the burden of this decision is being shared in an increasing degree with the government, the pharmaceutical industry still bears a major responsibility for interweaving the protection of the public and the need for continuing progress in the research, development and marketing of new and better drugs.

Purpose of Drug Research

The purpose of drug research is to acquire and interpret and apply reliable data which may lead to practical medical conclusions about new or currently used therapeutic agents, or bring about a better understanding of the body systems and the ways in which disease affects them. The object should not be to placate or please, avoid controversy, or shun possible lawsuits, but to gain knowledge whereby man may benefit. And there is nothing wrong with viewing research in a practical light, if it helps an industry grow or a profession become more proficient and thereby more self-sufficient.

The investigator engaged in clinical research who wishes to live peacefully with his conscience is always concerned with the safety, as well as the improved welfare of his subjects. So is the responsible sponsor of a remedy under study, be he manufacturer or other interested party. The researcher tries to design his experiments to obtain the maximum information with the least risk to the smallest number of patients. In this approach he is supported by the sponsor. Both should and do seek the advice of others as indicated. Thus scientific knowledge, integrity, consultation and a deep-seated conscience serve as guides for those who inquire about new and better remedies.

Use of the Drug

Then there comes a day when the remedy is ready for wider use. This is when the education, training, experience and judgment of the prescriber determines the wise, effective and safe use of the drug, for without this even the best drug will fall short of expectations. But to an important extent such use also depends on the wisdom, attentiveness and response of the patient as he follows instructions or tries to evaluate independently emotion-disturbing headlines about doctors, drugs and drug makers. Unfortunately for all, there are occasions when knowledge seems to outrun wisdom to use it.

Often one hears about an individual's right to do something. Well, with right to do something must be an awareness of responsibility when the right is exercised. This certainly is true for the health

professions and drug manufacturers. But it also is true for the legislator, administrator, regulator and for the public at large.

Responsibility and Rights of the Drug Manufacturer

The drug manufacturer has the responsibility of making useful drugs, prepared in the light of good quality control, and marketed with truthful statements. In addition, as a businessman the drug manufacturer should expect the privileges shown to all businesses in a law-abiding community. If he as a manufacturer and distributor of a drug meets such standards, and in addition assumes the special obligations of one in a specialized area of interest as all inclusive as health, he should have the right in the truest sense of the word to look for, manufacture and promote the use of new medicines. And he has a further right to expect qualified people to use his products if they can be persuaded to realize the existence of previously unmet needs or the uniqueness of his product or the integrity of his name.

The manufacturer of a drug has a special mission in life if his goals are progress, growth and public contribution. He must depend on research even more than promotion if he is to achieve these goals and hold them. For without this exploring of the unknown, he can be certain that to mark time is an act designed for those who are suicidally-minded businesswise. His is a trust shared by the professional man looking for new ways to heal ailing bodies, by those on whose bodies the healing will occur, and by the investing public as it puts to work its available cash to help this part of our life grow.

Since the prescription drug industry alone now represents between $3 and $4 billion a year, has more than 100,000 employees in the United States and more than 50,000 abroad, has about five million stockholders and spends almost $300 million a year in research to ferret out 150,000 to 200,000 compounds or more each year of which only 30 or 40 will be put to practical human use within five, six or seven years, it seems not unreasonable to expect the industry to plead for certain rights. But they are quite simple. Thus, the drug industry believes it should be trusted and respected as an industry; that it should not be subjected to discriminatory legislation concerning prices, patents, trademarks and other facets of normal business life; that it should be permitted to explore the unknown in science with its own scientists and with the voluntary help of others; that it should be permitted to reveal its findings and urge their application. The same reasoning applies to the nonprescription drug industry.

The drug industry also believes that the right to use new and older medicines is inextricably related to laws and regulations as well as professional judgment and competence where drugs are concerned. But it believes that such laws and regulations should be intended to aid the public, not to hold back new treatments; to assist the health professions where public health is concerned, not to impede their administration or subject them to unnecessary restrictions, harassment or risk of court actions; and that their promulgation and application should not result in emotional imbalance or hysteria, so that the public itself suffers the most from mistaken appraisal, misleading confusion or refusal to cooperate with the prescriber. In this respect, the eager administrative official and the improperly informed public official would be wise to heed the advice of those who are more professionally competent.

And finally, the industry also believes that since the practice of medicine is not yet an exact science and since the body cell is often unpredictable from body to body, even hour to hour, there should be proper recognition of the fact that differences of opinion in medicine over usefulness of product and technic will continue long after all of us here today are gone. The bedside approach to the sick person is still more dependable than slide-rule application from a protected armchair. Differences of opinion simply must be recognized, appreciated and accepted when such differences emanate from well-informed and medically accepted sources. Otherwise, decision making for the majority of the sick may well cause worsening or even death for a minority of the ill, as legislators, regulatory officials, hospital administrators and welfare agencies attempt to apply formulas, rather than reason to matters involving the use of new medicines.

Frequently in these comments there has been reference to the prescription drug industry. This is because the speaker is more familiar with this part of the drug industry and is not so impudent that he would dare attempt to outline in detail the rights and responsibilities of others. But at the same time he believes that there is much in common between those who make prescription drugs and those who produce nonprescription items, the need for research being one. Not only is there a need for research for progress, but also a need for research to substantiate so many of the views now being questioned. In fact, there is even need for increasing the recognition of the need for research, particularly by those whose training and business or professional activities do not encourage an enlightened appreciation of the role of research in modern society.

Research Is Essential for Survival

Research today is a word that must appear in the business and professional life of the drug industry. It always has been thus for those with lasting progress in mind, but today research is necessary for more than growth; it is essential for survival. Public opinion, governmental scrutiny, professional questioning and business competition demand continuing appraisal of what business management thinks it knows. This is more than a question of establishing a demonstrable fact, for example, the use of a drug for a mental condition. It used to be sufficient to demonstrate that something was useful, when and when not. Now, however, one must learn, if possible, why it is effective, and sometimes why it is not; how it compares with other agents with similar medical appeal; its potential usefulness and acceptability as new scientific information is gathered; and a number of additional facts based on study. In other words, the sustained maintenance of a drug in today's medical armamentarium rests on periodic, sometimes continuing, examination and re-examination if general acceptance is to be obtained. And if there is any doubt in anyone's mind about this growing requirement, he should pause just long enough to consider, among other things, some recent Senatorial investigations and allegations, some pronouncements and expressions of opinion from regulatory agencies, various newspaper headlines of recent vintage, and interpretations of amended laws, such as the so-called grandfather clause, effective in October 1964, which bears on proved usefulness.

Middlemen in the Research Team

Research used to be a matter of interest essentially between the researcher and those who put it to practical use. Sometimes it seemed interesting to some of those who benefitted from the practical application, but in general they accepted it without much question, even though they did not understand it other than to appreciate the fact that it was good for them. Now, however, there are middlemen in this researcher-applier-user team. The government is a middleman. So is the lay press. So on occasion is the academician, and at times there are others. The interest of these middlemen range from assigned areas of interest to self-appointed interests.

Research Today Must Meet New Demands

As a result of influencing participation by the uninformed, problems do arise. Public opinion, competition and laws and regulations unquestionably have influenced the need for research in the drug field.

No longer is it sufficient to search for new products or new uses to grow. To just stand still even, one now must do research to support previous observations, and the treadmill is gaining speed all the time. There is need today for more and more complete, sounder research. This should not be construed as a suggestion that research in the past was not sound or complete. It merely is intended to emphasize that research today must be designed to meet new needs and to include recent information. In fact, there may be a greater need at times for application of the word *re*search than for the use of the word search.

In the past there was more searching than researching. Today there is an overwhelming need for true researching even as the searching continues. The recent amendments and regulations from Washington alone make this abundantly clear even if good business judgment did not. What is emanating from Washington in the way of research demands is not just a proposal; in effect, it is a law.

Factors Affecting Changes in Regulations

What changes are needed in regulations or interpretations of some of these regulations will depend on three factors: tests in the courts, new research findings, and the loud, protesting voices of informed, qualified and respected scientists and practitioners. The strength of such dependence will rest on the aggressiveness with which these factors are pursued. Without facts, it will be almost impossible to win decisions that involve health. The intermingling of public need, business and professional responsibility, legislative appeal, headline fabrication and Parkinson's law for growth in government creates a formidable opponent for those without facts to support their points of contest. This is true at federal, state and local levels as laws, regulations, administrative decisions and personal opinions become evident. Furthermore, in an emotional issue such as health, where fear of error in judgment may become as important as personal bias, there will be increasing attempts to reduce the shades of grey. The publicly exposed administrator or official will want just black and white decisions. Unfortunately, the unpredictable body cell does not realize the problems it creates by not doing what the legislator, regulator or administrator claims it should do.

Practical Challenges Arise from Today's Research

There are some practical challenges that arise from research in today's modern setting. For example, management as well as the

research department must support research even though at times it may seem too much like retracing old steps. Researchers may have to be strongly urged to do research that seems to have little glamor associated with it. This will be particularly true at the clinical level. When these researchers are urged to respond to such appeals, they should be remembered as men and women who have special interests and needs, particularly in other research areas where support may be lacking. Research offers the appeal of a two-way street if selfishness does not dominate the movement of traffic.

Research concerning human health needs cannot be determined by applying slide-rule technics. Research does not have the precision of mathematics and may never have it if our knowledge continues to increase. Among the elements that may cause a moratorium on progress in this country discouraging all but competitors elsewhere, are attempts to define tests too narrowly, or to classify good investigators as qualified or unqualified according to academic background or institutional affiliation, or to rate institutions, rather than judge the abilities of the man therein, or failure to distinguish between etiquette, ethics and law, or to share available information that is not of a fundamental confidential nature, or to persuade legislators, educators, regulators and others of their broad responsibilities to others, rather than to their narrowly confined interests, or to reveal to all, but particularly the public, the relationship between research and benefits. Thus the relationship between research and benefits includes more than the lessening of suffering and the saving of lives. It bears on patents, tradenames, freedom of choice, profits—well, it bears on anything that in the long run results in progress for more than those with personal interests in discovery or application of discovery.

Business and professions, like other parts of the American scene, should be self-regulated whenever this is practical. It is a less expensive, less stifling, and more productive approach to daily problems and needs. Unfortunately, the battle lines in this country seem to be becoming more sharply defined with government enterprise on one side and private enterprise on the other. Unfortunately also, there are still some who fail to appreciate that they are part of private enterprise and if government becomes so big that it assumes all responsibilities for the population, they will lose such freedoms as selection of place of study, selection of health counselor, selection of place and kind of business, and a host of other things that students, homemakers and union members now enjoy, as do teachers, business people and other professional groups.

It may well prove to be that through research in the medical field, which is an ever increasing necessity, there will emerge the kind of voluntary, cooperative, self-policing leadership that will lessen the demand for regulations and legislation. It is conceivable, too, that those in the health field who have recently been sharing the spotlight of public attention may in time be able to spend more time on creating progress and less on repair of damages. Probably it is too much to hope that the businessman will be loved by all, but at least he should be able to expect and work for public understanding, acceptance and respect. In fact, this is the type of public image that will contribute more to progress, even if it carries with it some anonymity, than will affection without respect. The drug industry through research and its application has an unique opportunity today to help affect public understanding and thus affect its public image. I hope we do not lose it through lack of foresight and courage to support our convictions about what is needed and how to meet this need. [The End]

PARNATE WILL RE-ENTER MARKET UNDER REVISED LABELING

The Food and Drug Administration has announced that it has accepted a drastic revision of the labeling of the drug Parnate (tranylcypromine) which will allow this drug to re-enter the market for use only in severe cases of mental depression.

A hearing to consider whether the drug could return to the market under its previous labeling has been cancelled by agreement between the manufacturers and the FDA.

FDA's acceptance of the proposed label changes was based on study of the world's medical literature on the drug, evaluation of controlled studies conducted with the drug, and a consideration of the views of top experts in the field of psychotherapy.

FDA said that two major issues had to be resolved: first, how toxic is the drug; second, does its effectiveness justify its use despite the known hazards? Since the drug is intended for the treatment of severe depression in which suicide is possible and in which electroshock therapy may sometimes not be used, the conclusion has been reached that the hazards—including the possibility of strokes and even some deaths—were justified. These hazards can be minimized and substantially avoided by careful use of the drug, FDA said.

Restrictions to be imposed include reduction of dosage and that the drug is not to be used except in hospitalized cases of severe depression, or in cases outside the hospital in which other medication has been found ineffective. It is not to be used by patients over 60 years of age or with any history of hypertension or other cardiovascular diseases. Experts from both the National Institute of Mental Health and from Saint Elizabeth's Hospital were consulted by FDA and concurred in the action taken. The manufacturer told FDA that it will be four to six weeks before the drug will again be available to the medical profession. It has been agreed that the full text of the revised labeling will be mailed to all physicians.

A New Vital Influence in International Food Standards

By NATHAN KOENIG

This Paper Was Presented at the International Food Standards Symposium, Twenty-Fourth Annual Meeting of the Institute of Food Technologists, at the Sheraton Park Hotel, Washington, D. C., on May 25, 1964, by Nathan Koenig. He Is Chairman, United States Food and Agriculture Organization Interagency Subcommittee on Codex Alimentarius and Special Assistant to the Administrator, Agricultural Marketing Service, United States Department of Agriculture, Washington, D. C.

NEVER BEFORE IN HISTORY has there been the multitude of international, regional and industry bodies and other organizations concerned with the promulgation of standards in the food field that we now have functioning in different parts of the world.

In 1962 the Food and Agriculture Organization of the United Nations listed 135 organizations and instrumentalities other than governments, as working on international food standards and related problems. And at that time, FAO pointed out this was not a complete list. The standards work of these 135 bodies alone ranges through the entire food field and includes every aspect from standards governing sanitation, sampling, analysis, additives and pesticide residues to standards of identity and quality.

Pace of International Food Trade Accelerated

In recent years the development of trading areas throughout the world, improved transportation facilities, and new food technology have all accelerated the pace of international trade in food. This brought about a new urgency for the establishment of standards that would facilitate international trading and also provide essential safeguards for protecting consumer health and insuring fair practices in food trade.

Many organizations and groups responded to meet the expanded and intensified need for various food standards. Many new bodies

also came into being to promulgate standards. As a result of this great build-up, much of the work carried on has encountered duplication, confusion and conflict. The need to simplify and harmonize international food standards work on a broad basis soon became apparent and there was a growing demand for corrective action. The response came through the leadership taken by the FAO and the World Health Organization in establishing a joint program on food standards. This program is being carried out through the Codex Alimentarius Commission, which is now in its first year of operation.

The basic purpose of the Codex Alimentarius Commission is to simplify and harmonize international food standards work by allocating priorities in the development of standards, by coordinating and supplementing the work of other bodies in this field, and by providing for finalization of draft standards at the government level and their publication in a consolidated Codex Alimentarius.

Unification of European Legislation on Food

The concept of an international body that would assume leadership in simplifying and harmonizing international food standards so as to facilitate trade and at the same time protect the interest of consumers in wholesome foods dates back about a decade. It was Dr. Hans Frenzel, a former Minister in the Austrian government, who advanced the idea of unification of European legislation on food in June 1953 at a meeting of the Research Group of the German Food Industry held at Bad Neuenahr.

Dr. Frenzel's proposal assumed a more concrete form in October 1954 on the occasion of the conferment of the Werder medal in Berne, when an Austrian delegation, in the presence of representatives of several countries, held a series of short lectures. The lectures dealt with the subject of bringing about the suggested unification and the effects of such an undertaking on the quality of food, the protection of the consumers and the promotion of international trade. This idea met with great interest, and encouragement came from many European countries.

Many lectures were delivered by Dr. Frenzel to explain his proposal for the unification of food legislation through the establishment of a Codex Alimentarius, and he did so quite successfully. As a result, in June 1958, the European Council of the Codex Alimentarius was established in Vienna following a preparatory meeting held in Paris the previous April under the auspices of the Commission

Internationale des Industries Agricoles which had been founded in 1934. Dr. Frenzel was elected first President of the Council.

It is interesting to note that at the time of the inception of the European Council of the Codex Alimentarius certain governments took the position that functions relating to the Codex Alimentarius could be absorbed into the activities of existing international organizations, particularly FAO and WHO. Thus, the statutes of the European Council were drafted in such a manner as to permit the absorption of the activities of the Council by one or more general international organizations.

With the growing focus of attention on problems of international trade, the integration of markets into regional groups, and the growing number of food standard programs undertaken by many organizations, including newcomers in the field, the problem of coordination and harmonization of food standards work again came to the fore in October 1960 in Rome at the first FAO Regional Conference for Europe. Out of the discussion that took place resulted this statement by the Conference:

> . . . a valuable step forward would be achieved if the Director General of FAO, in collaboration with the Director General of WHO and after consultation with the international governmental and non-governmental organizations active in this field, could submit to the Eleventh Session of the Conference proposals for a joint FAO/WHO program on food standards and associated requirements, with particular reference in the first instance to the principal foodstuffs offered for sale on the European market.

Joint FAO-WHO Program Initiated

Following discussions with the European Council of the Codex Alimentarius, FAO undertook to develop a joint FAO/WHO program on food standards in keeping with the views expressed at the first FAO Regional Conference for Europe. In February 1961 the European Council of the Codex Alimentarius formally authorized its presidial body to enter into an association with FAO and WHO.

At the Eleventh Session of the FAO Conference in November 1961, formal action was taken by FAO initiating a joint FAO/WHO program on food standards. This provided for the establishment of a Codex Alimentarius Commission open to all member nations and associate members of FAO and WHO who are interested in international food standards. The work of the Commission was to be financed out of a special Trust Fund into which would be received contributions from participating countries. The FAO action, later

concurred in by the WHO Executive Board, also called for holding in 1962 a joint FAO/WHO meeting of government representatives in order to review the proposed program of food standards and to draw up recommendations for future activities in this field.

The meeting of government representatives to consider the proposal for establishing a Codex Alimentarius Commission under the joint auspices of FAO and WHO was held in Geneva, October 1-5, 1962. A total of 44 countries and 24 international organizations were represented.

The need to develop and simplify work on international food standards, both on a worldwide and regional basis, was fully reviewed. The Geneva meeting endorsed the proposal for a joint FAO/WHO program on food standards and the establishment of a Codex Alimentarius Commission for carrying on the work. Guidelines for the work of the Codex Alimentarius Commission were developed and priorities established. It was agreed that the first session of the Codex Alimentarius Commission should be held at FAO headquarters in Rome. The date later set was June 25 to July 3, 1963.

Some 120 participants, including the representatives of 30 countries and observers from 16 international organizations, attended the First Session of the Codex Alimentarius Commission that met in Rome in mid-1963.

Development of Rules of Procedure

With the guidelines developed at the Geneva Conference in October 1962, the First Session of the Codex Alimentarius Commission, meeting less than a year later, had the basis for developing its Rules of Procedure and its general program of work.

One feature of the Rules of Procedure is a provision for establishing subsidiary bodies, including Expert Committees, for the preparation of draft standards and setting up advisory groups for a given region or group of countries specifically enumerated by the Commission. Under this provision the Commission established an Advisory Group for Europe with the European Council of the Codex Alimentarius agreeing to serve in this new capacity under the name "Advisory Group for Europe of the Joint FAO/WHO Codex Alimentarius Commission." As such, this body became an organ of the Commission and it was determined that participation would be open to all member governments of FAO and WHO within the geographic area of Europe, including Israel, Turkey, and the USSR.

Also in keeping with the Rules of Procedure, the Commission appointed a Coordinator for Europe who, under the terms of reference, is advised and assisted by the Advisory Group for Europe on all matters concerning the preparation of draft standards for submission to the Commission. The function of the Coordinator for Europe is to advise and assist the chairman of Expert Committees based on countries in Europe in their common work on food standards throughout the region. The Coordinator for Europe is also ex officio Chairman of the Advisory Group for Europe.

The Commission also adopted a number of "guiding principles" for use by its Expert Committees and other bodies preparing draft standards for its consideration. The general aim is to arrive at standards that are both practical and meaningful from the standpoint of trade as well as consumer interests. So-called "recipe" standards are to be avoided.

Through discussion and debate at the Rome meeting the principle was firmly established that the food standards work of the Codex Alimentarius Commission should be on an international basis and only in those instances where no other alternative was available (primarily in the case of highly perishable commodities) should standards be on a regional basis and then recognition must be given to equivalency of products coming from outside the region.

Financing of Commission's Work

The Commission also reviewed the Trust Fund method of financing the food standards program and recommended that the costs involved should be covered by the regular FAO and WHO budgets as soon as the different budgetary procedures of the two organizations would make this step practicable. This recommendation was discussed at the recent conferences of FAO and WHO and is expected that financing of the Commission's work will be covered by the regular FAO and WHO budgets in about two years, which has been indicated as the earliest that the required action can be taken. In the meantime, the financing of the work of the Codex Alimentarius Commission from contributions to the Trust Fund poses a problem, not only for the program itself, but also for many of the participating countries.

Work Accomplished

To get its program of work under way, the Codex Alimentarius Commission allocated preparatory work on draft standards, largely

in accordance with the list of priorities previously established by the joint FAO/WHO conference held in Geneva in 1962. The assignments were made either to *ad hoc* Expert Committees established by the Commission or to existing outside specialist bodies. As a result, the following work is now being done:

(1) As a result of its offer accepted by the Commission, the FAO Fisheries Division has assumed leadership in preparatory work looking toward the establishment of a code of principles concerning fish and fishery products and associated individual standards. A meeting of fisheries experts was held February 18-20, 1964, in Rome under the auspices of FAO with representatives of 12 countries actively participating. The report and recommendations resulting from this meeting will be considered at the next session of the Codex Alimentarius Commission.

(2) The United Kingdom chairs a worldwide Expert Committee on Oils and Fats. This Committee has the responsibility of elaborating draft international standards for oils and fats of animal, vegetable, and marine origin but excluding margarine and olive oil. Its first meeting, held in London, February 23-28, was attended by representatives from 12 countries and 7 international organizations. Draft standards developed at this session are now being reviewed by country representatives who took part in the meeting. Later in the year a second meeting of the Expert Committee on Fats and Oils will be held to prepare final drafts of standards for presentation to the Commission.

(3) A worldwide Expert Committee on Sugars is chaired by the United Kingdom to develop draft international standards covering all types of nutritional sweeteners other than honey. This Expert Committee held its first meeting in London, March 3-5, with representatives from 10 governments and 4 international organizations attending. Draft standards developed as a result of the meeting are currently being reviewed by those who participated in the session. The completed draft standards will be submitted to the Commission for consideration at its next meeting. A second meeting of the Expert Committee will be held, possibly in November 1964, to discuss standards for the sugars not covered at its first meeting.

(4) The development of fruit juice standards by the Working Party on the Standardization of Perishable Foodstuffs of the Economic Commission for Europe is now being carried on jointly with the Codex Alimentarius Commission. The first meeting involving

joint participation by ECE and the Commission to consider draft standards for fruit juices was held April 6-10 in Geneva with representatives from 13 countries participating. When agreement is reached on fruit juice standards, they will be submitted to the Commission for finalization under its procedures.

(5) Switzerland is chairing an Expert Committee on Cocoa Products and Chocolate. The first meeting of this group was held in Neuchatel, Switzerland, November 5-6, 1963, with representatives from 9 countries participating. A second meeting of the Committee was held this year in Montreux, April 22-24, and representatives from 10 countries took part in the deliberations.

(6) An Expert Committee on Food Additives is functioning under the chairmanship of the Netherlands. The task of this Committee is to develop draft lists of acceptable additives and to survey and designate wherever possible proposed maximum levels of use for these additives in individual foods. The first session of the Expert Committee on Food Additives was held at the Hague, May 19-22.

(7) The United States is serving as chairman of an Expert Committee on Food Hygiene. The first session of this group was held in Washington, May 27-28, to consider the development of draft hygiene standards for foods other than meat and milk and milk products. Hygiene standards for meat are to be developed by the existing Joint FAO/WHO Panel on Meat Hygiene since it is the Commission's advisory body on this subject. Questions concerning milk hygiene are within the terms of reference of the Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products. This Committee of government experts is considered by the Commission as having exclusive competence for all questions concerning milk and milk products and is treated as a Committee of the Whole of the Commission.

(8) The United States is also chairing a worldwide Expert Committee on Processed Fruits and Vegetables. This Committee is responsible for developing draft standards for all types of processed fruits and vegetables, including dried products and jams and jellies. The first meeting of this Expert Committee is being held here in Washington this week, May 29-30.

(9) A worldwide Expert Committee on Meat and Processed Meat Products is under the chairmanship of the Federal Republic of Germany. This Committee is to develop proposals for:

(a) Classification and grading for carcasses and cuts of beef, lamb, mutton, pork and veal;

(b) Definitions, labelling and other requirements for such processed meat products as may be deemed desirable at this stage.

This Expert Committee is obligated to work in cooperation with the Joint FAO/WHO Committee on Meat Hygiene.

(10) A worldwide Expert Committee on Pesticide Residues is also being chaired by the Netherlands. This Committee has the responsibility of surveying and proposing, where possible, tolerances for pesticide residues in individual foods.

(11) Austria is chairing a worldwide Expert Committee to develop draft international standards for honey.

(12) A worldwide Expert Committee on Methods of Analysis is also under the chairmanship of Austria.

(13) The International Standards Organization, at the request of the Codex Alimentarius Commission is developing methods of sampling for physically similar product groups and, where necessary, specific methods for important individual products. The ISO is to make a progress report in time for the Commission's consideration at its next session.

(14) The Secretariat of the Codex Alimentarius Commission is drafting for submission to the next session a concise resume of food labelling laws, particularly those in countries participating actively in the work of the Commission. This resume is to cover provisions dealing with identity, net contents designations, indication of manufacturer, and special requirements on type and style of label declarations.

(15) At the request of the Commission, the United States is preparing a background study on standards for poultry. Work on this is nearing completion and is to be submitted to the Commission in time for its next session when the question of draft standards for poultry, an important product in international trade, is to be taken up.

(16) The International Federation of Margarine Associations is developing a draft standard for margarine for early submission to the Commission.

(17) The possibility of developing draft standards for eggs is to be considered at the next session of the Codex Alimentarius Commission when more information is expected to be available on the program of standards work undertaken by the International Egg Commission.

(18) At the request of the Codex Alimentarius Commission, the United Kingdom is preparing a background paper on soft drinks for consideration and possible further action as the next session of the Commission.

(19) Responding to a request of the Commission, the International Standards Organization is making a survey of work being done by several interested organizations on methods of sampling and analysis for wheat. The results of this survey are to be made available for submission to governments in good time before the next session of the Commission.

Plans for Second Session

At its next session, the Codex Alimentarius Commission will consider in second reading draft standards on which governments participating in its work have already submitted their views and comments. These draft standards were drawn up before the Commission was constituted, and at its meeting in Rome last year, were considered in first reading and then referred to governments for detailed comments. These drafts involve standards for:

(a) Cocoa beans prepared by the Working Party under the FAO Committee on Commodity Problems;

(b) Olive oil drawn up by the International Olive Oil Council;

(c) A number of fresh fruits and vegetables drafted by the Economic Commission for Europe;

(d) Edible fungi, a text prepared by the former European Council of the Codex Alimentarius, now the Advisory Group for Europe of the Joint FAO/WHO Codex Alimentarius Commission, and an extract from the draft Latin-American Food Code;

(e) Sampling, text prepared by the former European Council of the Codex Alimentarius;

(f) General principles, two texts, one from the former European Council of the Codex Alimentarius, the second extracted from the draft Latin-American Food Code;

(g) General principles for the use of food additives, text prepared by the Commission Secretariat from reports of the Joint FAO/WHO Expert Committee on Food Additives; and

(h) Permitted lists of food additives, four texts, prepared by the Commission Secretariat on the basis of the reports of the Joint FAO/WHO Expert Committee on Food Additives.

The Second Session of the Codex Alimentarius Commission will be held in Geneva, Switzerland, September 28—October 7, 1964. This session will be largely concerned with the detailed consideration in second reading of the draft standards on which comments have been received from governments. It will also be concerned with the reports on work accomplished by Expert Committees and other specialist groups to which the Commission last year made assignments for promulgating standards and developing drafts of various background papers.

It is expected that as a result of the Commission meeting certain draft standards will be ready for submission to governments for consideration and comment. This is in accordance with the Rules of Procedure and enables all participating governments to express their views on proposed standards which may subsequently be accepted by the Commission for inclusion in the Codex Alimentarius. The prior submission of the draft text of any standard to all members of the Commission applies both to international standards as well as to any standard primarily intended for a region or group of countries. This is an important safeguard for the interests of all concerned, either directly or indirectly.

Aims of Codex Alimentarius Commission

The Codex Alimentarius Commission represents a new and vital influence in the realm of international food standards. A general observation of basic importance is that a food standard, when appropriately supported and backstopped by practical standards for sampling, analysis and other requisites, should aim at ensuring the market of a sound, wholesome product, correctly labeled and presented. It should not be intended to affect consumer preference, but should aim at ensuring that the consumer can know what he is buying.

These purposes served by a standard are especially important in providing buyers and sellers with a common language for local and long distance trading and a yardstick for determining value. Otherwise, the use of widely varying standards, particularly among countries, leads to misunderstandings and confusion in international trade, undue restrictions in trade, and added marketing costs.

The leadership of the Codex Alimentarius Commission in simplifying and harmonizing international food standards also provides the guidance and coordination which are so greatly needed among all groups, including governments, engaged in the elaboration of such

standards. Thus the work of the Commission merits full support for the opportunity that it offers in developing equitable food standards and thereby combating the use of standards for purposes of impeding or restricting international trade, thereby providing essential safeguards for both buyers and sellers as well as consumers. This calls for essential backing and cooperation not only from governments and the various independent bodies engaged in international food standards work, but also from private industry, business, trade, agriculture and the general consuming public. [The End]

FDA DRUG INSPECTORS TO ATTEND UNIVERSITY TRAINING COURSE

The first university training course on drug manufacture for federal drug inspectors was announced on June 19 by the Food and Drug Administration, Department of Health, Education and Welfare, and the University of Rhode Island. The course will be held in the University's new Fogarty Health Science Building, which contains a modern pilot plant with the latest drug manufacturing equipment. It is the newest such facility in the country.

The initial three-week program which begins on July 6, 1964, in Kingston, Rhode Island, has been planned by Food and Drug Commissioner George P. Larrick and Dr. Heber W. Youngken, dean of the URI College of Pharmacy.

Commissioner Larrick said the course is designed to broaden the FDA inspectors' knowledge regarding pharmaceutical principles, manufacturing techniques, and control procedures. "While in the past FDA has trained its drug personnel within the agency, it is now calling upon universities to supplement this training," Mr. Larrick said. He cited as another example, the beginning of the FDA Institute for Advanced Analytical Chemistry last January at Georgetown University in Washington, D. C.

Dean Youngken noted that advances in technology and new drug laws create more responsibility for drug inspectors and require greater knowledge of laboratory procedures, testing and controls, and the equipment used. The FDA inspectors, he added, will be familiarized with the basic principles and terminology of the many dose forms and pharmaceutical methods used by industry with particular emphasis on manufacturing and control procedures. The fundamentals will be learned, he explained, by actual participation in pilot plant drug manufacturing operations, such as are now part of the URI College of Pharmacy program.

The FDA-URI curriculum will be offered three times during 1964. Each class will enroll approximately 25 FDA inspectors from around the country. All FDA inspectors are college graduates—some with masters' degrees—so the program will be an intensified one. Cost of the sessions—estimated to be about $3,000 each—will be met by the FDA.

Both Commissioner Larrick and Dean Youngken said they expect to enroll state and city drug inspectors in future courses.

A New Look at Cooperation in Complying with Food Laws

By FRANKLIN M. DEPEW

Mr. Depew, President of The Food Law Institute, Inc., Presented This Paper Before a Meeting of the Flavoring Extract Manufacturers' Association in Palm Beach Florida, April 14, 1964.

FOR SOME TIME NOW you will have noted a gradual shift from an emphasis placed on punitive measures in the enforcement of our food, drug and cosmetic laws, to an emphasis placed on education and cooperation with the regulated industries coupled with a judicious regulatory program. Self-policing through cooperation and understanding has now become a major area of enforcement. This has included an opportunity for discussion before any drastic action is taken on minor violations not related to health hazards. This has restored a mutual understanding, trust and respect which was not as high as it should have been a few years ago.

Among the steps recently taken by the Food and Drug Administration was the creation of a new Bureau of Education and Voluntary Compliance, under Shelbey T. Grey, who is deputy director and acting director. The new bureau includes a Division of Industry Advice (formerly in the Bureau of Enforcement), with an Advisory Opinions Branch, Harold F. O'Keefe, chief, and an Industry Information Branch, Jonas Bassen, chief, to answer industry inquiries on compliance problems. It also includes a new Division of Consumer Education, which is now headed by James L. Trawick. This new division is made up of three branches: a Consumer Information Branch, Miss Mary E. Cunningham, chief; a Consumer Consultant Branch, Mrs. Carla S. Williams, chief; and a Consumer Survey Branch for which no chief has yet been appointed. We in the Food Law Institute believe the steps taken will result in improving the exchange of information between government and industry, government and consumers, and between industry and consumers.

Food Industry Liaison Committee Formed

In addition, the suggestion that a food industry liaison committee be established, made for a number of years at the Food and Drug Administration-Food Law Institute Joint National Conferences, was acted on last year and a seven-member committee, of which I am a member, was inaugurated. This committee seeks to improve voluntary compliance and to promote a better-informed administration of the pure food law. We join with the Commissioner of Food and Drugs, George P. Larrick, in high hopes for this committee's future activities.

This shift in emphasis has been brought about, in my opinion, by the creation of a political atmosphere favorable to this desirable development. I believe it can be said without fear of contradiction that all the Commissioners of Food and Drugs, from Walter G. Campbell to George P. Larrick, have concluded that education can be utilized to greatly increase the effectiveness and benefits of a law enforcement program. That this is so is confirmed by the statement of Mr. Larrick before the Section on Food, Drug and Cosmetic Law of the New York State Bar Association on January 22, 1963,[1] when he said:

> It has been the objective of the administrators of the Food, Drug and Cosmetic Act from the very beginning to administer the statute in such a way as to prevent violations of the law rather than to punish violators after they occur. We will always, in my opinion, need to employ the sanctions of the statute to effectuate its purposes, but recent developments, both in the amendments mentioned as well as in the reviews of our administrative programs by the Citizens Advisory Committee and others, have emphasized that administrative actions designed to implement preventative enforcement should be undertaken at an accelerated pace. This we plan to do. We welcome your constructive suggestions and participation in this endeavor.

If this has been the philosophy of the Commissioners of Food and Drugs, it may well be asked, why from time to time has the Food and Drug Administration concentrated on its enforcement and police power activities to the neglect of cooperation with industry in programs aimed at improving consumer protection. A partial answer would seem to be that all too often the Congress or the general public raises an uproar of criticism of the apparent de-emphasis of enforcement, charging that this undermines the FDA's basic mission. Thus, the Commissioner and his staff need the support of outstand-

[1] George P. Larrick, "Administering New Food and Drug Laws," 18 FOOD DRUG COSMETIC LAW JOURNAL 133.

ing and dedicated men from both industry and the universities if they are to effectively implement the philosophy of education.

At the present juncture, we are fortunate that the Second Citizens Advisory Report on the Food and Drug Administration, filed with the Honorable Anthony J. Celebrezze, Secretary of Health, Education and Welfare, on October 25, 1962,[2] emphasized that FDA needed to develop still better approaches along preventive lines of enforcement. We are fortunate, too, in that Boisfeuillet Jones, Secretary Celebrezze's Special Assistant for Health and Medical Affairs, believes in education and government-industry cooperation, as indicated by his remarks on the occasion of the FDA-FLI Joint National Educational Conference on November 26, 1962.[3] However, we cannot afford to be complacent. The First Citizens Advisory Committee Report[4] had strongly recommended the educational approach and back on May 10, 1955, Bradshaw Mintener, then the new Assistant Secretary of the Department of Health, Education and Welfare, stated at the Fifty-Ninth Annual Conference of the Association of Food and Drug Officials of the United States,[5] that there is "a growing realization by officials that education can be utilized to increase greatly the effectiveness and benefits of a law enforcement program . . . ." Nevertheless, the Second Citizens Advisory Committee criticized the FDA for failure to take adequate measures to implement the recommendations of the First Citizens Advisory Committee regarding education. Thus, it seems clear there was a deterioration in the program of education between 1955 and 1962. What has happened once can happen again.

What can we do to avoid a recurrence of such an unfortunate condition? Responsible industry must educate itself so as to be better able to understand and perform its function of bringing safe and properly labeled foods, drugs, devices and cosmetics to the consumer. It is important that all industry decisions relative to compliance with this law should be made with the recognition that their business has placed them in a position of public trust. No compromise can be

[2] "The Second Citizens Advisory Committee Report on the Food and Drug Administration," 17 FOOD DRUG COSMETIC LAW JOURNAL 581.

[3] Boisfeuillet Jones, "Consumer Protection Activities," 17 FOOD DRUG COSMETIC LAW JOURNAL 808.

[4] "Report to the Secretary of Health, Education, and Welfare, June 1955, by the Citizens Advisory Committee on the Food and Drug Administration," 10 FOOD DRUG COSMETIC LAW JOURNAL 453.

[5] Bradshaw Mintener, "Education Versus Enforcement," Quarterly Bulletin, Food and Drug Officials of the United States (July 1955), p. 107.

made where the public health is involved. Solutions to other problems must be sought with a high degree of political maturity and statesmanship. Industry must use its stewardship responsibility in such a way that it becomes a constructive, rather than a destructive, force. If industry will accept this responsibility, I believe we may expect to continue to receive the cooperation of the FDA and the state regulatory bodies as well.

Uniform State Weights and Measures Regulations Needed

A recent example of what responsible industry can do is the step taken to work with National Conference on Weights and Measures in an endeavor to secure uniform state regulations covering weights and measures requirements on minimum type size and placement of the net quantity statement on the label. The importance of the action taken consists in the industry recognition that a problem existed which was of such overriding importance to the consumer as to warrant the imposition of some additional restrictions in the freedom of action of the industries involved. A special committee was set up with Frank T. Dierson, general counsel of the Grocery Manufacturers of America, Inc., acting as chairman. Because the matter was of great interest to other industries, they too were afforded representation on the special committee. On February 17, 1964, Mr. Dierson, as chairman, presented the committee's report to the Laws and Regulations Committee of the National Conference on Weights and Measures in Washington, D. C. Members of this committee were impressed with industry's good faith and its formal contribution to the solution of a vexing problem. I understand committee members were generous in expressing their appreciation and promised careful consideration of the report. Thus, we may hope for a satisfactory outcome of this matter.

Miss Sylvia Porter was sufficiently impressed by the efforts of this industry committee to mention it in her nationally syndicated column, when she wrote:

> Today in Washington a new industry committee, representing all leading grocery producers and suppliers, is meeting with state weights and measures officials to draft a significant amendment to current state weights and measures laws. The amendment would require "prominent, definite and plain" statements of contents and define exactly how prominent, definite and plain those statements should be.

The lesson we learn from this is—if the factors of consumer protection outweigh the burdens which may be imposed, industry must

seek a solution which will protect the highest interests of all concerned. On the other hand, if the factors of consumer protection do not merit further restraint on industry's freedom of action, any proposal imposing such restraint should be opposed. However, it is most important that industry carefully weigh the two aspects of the matter in the light of its stewardship responsibility.

FDA Seeks Expanded Factory Inspection Authority

There is one current problem at issue between industry and the FDA which could disturb the confidence and trust which now exists, unless patience and tolerance are exercised on both sides. This is the problem posed by FDA's request for expanded factory inspection powers to include the right to inspect records, files, papers, processes, controls and facilities bearing on any violation of the Federal Food, Drug and Cosmetic Act. This authority has been granted in respect to prescription drugs by the Drug Amendments of 1962. I discussed this matter before you at your meeting at Skytop, Pennsylvania, on May 1, 1962.[6] In that talk I reviewed the history of the present law, the FDA's requested amendment and suggested a proposed solution which I thought might be acceptable to both the food industry and the government. I suggested legislation which would authorize FDA to require an affidavit from an official corporate representative stating that an examination of the company's formula cards and processing operations kept in the regular course of business, discloses that the food or color additive named is not used in excess of a certain stated amount. This would give FDA the needed information relative to these additives that they would secure from access to the records, but without disclosure of the other confidential information shown in the records.

That this proposal was not satisfactory to the FDA is evidenced by Winton B. Rankin's remarks before the FDA-FLI Joint National Educational Conference on December 2, 1963.[7] In that talk he urged that for the protection of the public, the FDA needed the same authority to make a complete inspection of records in a factory producing nonprescription drugs, foods, cosmetics and devices that had been granted the FDA by the Drug Amendments of 1962, and just last month Commissioner Larrick in his testimony before the House Government Operations Subcommittee urged the need for this authority.

[6] Franklin M. Depew, "Are Broadened Inspection Powers Necessary?" 17 Food Drug Cosmetic Law Journal 331.

[7] Winton B. Rankin, "Inspection Authority," 18 Food Drug Cosmetic Law Journal 673.

Because of the concern expressed by members of the bar about this problem, and in the hope that some middle course might be found, I, as chairman of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, and as chairman of the Division of Food, Drug and Cosmetic Law of the Section of Corporation, Banking and Business Law of the American Bar Association, appointed a special committee in each association to consider the problem. This committee is made up of some of the most able attorneys practicing in the field, namely: Frank T. Dierson, chairman, Kenneth E. Mulford, Edward Brown Williams, Edwin L. Harding, Michael F. Markel, James F. Hoge, Samuel A. McCain and George T. Scriba.

Industry's Management and Lawyers Oppose Expanded Authority

From my discussions with members of this committee, it would appear that these committeemen share the views expressed by one member, Edward Brown Williams, at the FDA-FLI Joint National Educational Conference on December 2, 1963.[8] His view was that such legislation would authorize an assault on the fundamental rights of privacy of those whose premises were inspected, and would constitute an erosion of their rights of liberty and of their privilege against self-incrimination. He felt strongly that the proposal would violate the tradition of fairness long found in our jurisprudence by authorizing unrestrained rummaging around in confidential papers and records. Members of the committee have told me that even if the authorization is justified in respect to prescription drugs to assure the public safety, this is an exception to the legislative philosophy of our free institutions which must be kept within due bounds. They reject the theory that intermittent examinations of records would have helped in any way in discovering the botulinus toxin that was found in canned and smoked fish, or in discovering excessive amounts of pesticides in the food processor's plant. Thus, industry management and industry lawyers seem to be united in opposition to expanded factory inspection authority for the FDA. They also seem united in their opposition to the present FDA policy, whereby inspectors are instructed to ask for formulas and other material to which they are not legally entitled.

[8] Edward Brown Williams, "Factory Inspection," 18 FOOD DRUG COSMETIC LAW JOURNAL 705.

The industry point of view was brought forcefully to my attention at the annual meeting of the New York State Bar Association last January when an attorney from upstate New York expressed his resentment about an FDA inspection of his client's plant. The inspector had asked to see all the plant records and they had been furnished to him. The plant manager reported the occurrence to the attorney at the end of the inspection. The attorney felt the inspection of these records constituted an outrageous violation of his client's elementary rights, whether the inspection was authorized by law or not.

Whether Congress will determine that industry's civil liberties should be curtailed by authorizing record inspection as in the interest of safeguarding the public health and safety is difficult to foretell at the present time. The President and his Assistant for Consumer Affairs, Mrs. Esther Peterson, seem to be convinced that the legislation is needed. They may thus be expected to support the staff of FDA in their efforts to secure this legislation. The argument for the proposal is perfectly understandable. It is a great advantage to the FDA and may improve public protection against dangerous foods, nonprescription drugs, cosmetics and devices. Industry representatives and attorneys generally may be expected to oppose the proposal for the basic reasons given by Mr. Williams.

Pending the outcome of this legislative struggle, which I do not think will be decided until 1965, I venture to offer the following advice to industry.

Industry Advised to Cooperate With FDA

Cooperate as fully with the FDA in a factory inspection in furthering the remedial purposes of the law as the circumstances permit. When the present factory inspection law was enacted, the method of enforcement contemplated by the Congress and those supporting the legislation was one of cooperation between industry and the FDA with the administrative officials assisting industry in self-regulation. The concept of preventive enforcement is strengthened by the additional provisions of the factory inspection law. Reports of violations uncovered during an inspection must be given to the manufacturer before the inspector leaves the plant.[9] Reports of analyses of

[9] Federal Food, Drug and Cosmetic Act, Section 704(b), 67 Stat. 477, FOOD DRUG COSMETIC LAW REPORTS ¶ 2663.

food samples taken during an inspection are required to be sent to the producer.[10] These provisions allow the manufacturer, in many instances by self-regulation, to correct the situation and to prevent the movement in interstate commerce of the offending article.

In this spirit of encouraging compliance, and of constructive cooperation, responsible industry should have no fear in making available to the field inspector all records which do not disclose confidential information. When the records do contain confidential information, serious consideration should be given to making the information available to the FDA's scientific staff in Washington, D. C., particularly if the FDA scientists can furnish good reasons why it is needed.

Perhaps if industry extended this cooperation to the FDA, its Bureau of Education and Voluntary Compliance could be persuaded to embark on a program of education which would explain in some detail why record inspection is felt to be necessary in respect of any particular substance or industry. I again suggest that if the problem of record inspection is attacked responsibly by both sides it is possible that industry and the FDA may find they can accommodate themselves to the present law with the conviction that they are fully carrying out the remedial purposes of the Federal Food, Drug and Cosmetic Act. [The End]

FDA PROPOSES WITHDRAWAL OF CERTIFICATION FOR ANTIBIOTIC TROCHES

The Food and Drug Administration has proposed to discontinue certification of 19 types of troches containing antibiotics on grounds of lack of substantial evidence of efficacy.

The proposal was published June 17, 1964, in the *Federal Register*. Interested persons have 90 days from this date in which to furnish any information which, in their opinion, demonstrates substantial efficacy of these drugs or to submit written comments to the Hearing Clerk, Department of Health, Education and Welfare, Room 5440, 330 Independence Avenue, S. W., Washington 25, D. C.

The proposal said that FDA medical scientists have evaluated information currently available with regard to the troches containing antibiotics, as well as the evidence available at the time the products were originally certified. They have advised that there is a lack of substantial evidence that the drugs are efficacious for the purposes claimed in their labeling. They are generally used for the temporary relief of minor sore throats due to the common cold. —FOOD DRUG COSMETIC LAW REPORTS ¶ 80,073.

---

[10] Federal Food, Drug and Cosmetic Act, Section 704(d), 67 Stat. 477, FOOD DRUG COSMETIC LAW REPORTS ¶ 2667.

Government and Industry — Are Their Objectives Dissimilar?

By VINCENT A. KLEINFELD

The Author Is a Member of Bernstein, Kleinfeld & Alper; Washington, D. C.

SOCIAL AND ECONOMIC conditions and problems are not immutable. What sufficed in Biblical days was inadequate in the days of the knight or, thereafter, in the days of the crossbow. In the dawn of human existence, people were too busily engaged in merely existing to develop industries and industrial processes. With the growth of cities, the scattered and small groups of those who sought protection from the barbaric hordes and marauders did not remain completely self-sufficient. It became necessary to obtain products, particularly food, from other sources.

It was the Industrial Revolution which enabled a limited number of manufacturing establishments to create commodities for the entire population, and a fairly small portion of the population engaged in agriculture to produce sufficient food to feed not only themselves but the cities. An inevitable accompaniment of the process was a stimulation in the growth of the industries in food and drugs. This development can be stated to have been retarded in this country. As stated, Europeans tended, from the Middle Ages on, to gather together in groups primarily for self-protection. The settlers who came to this country, however, were required to be practically self-sufficient in order to cope with the exigencies of pioneer life. It was an unusual household indeed which did not raise enough food and make enough clothing to be practically self-sufficient. But the end of the Indian Wars, the settlement and civilization of the entire area of this country, the tremendous growth of the population, and the rapid increase in our transportation and communication systems and industrial processes soon changed this. The entry of the state into this picture, therefore, in order to safeguard the supply of foods and drugs, was unavoidable. Regulatory legislation did not, like Pallas Athene who sprang fully grown and armed from the head of Zeus, suddenly come to pass. It was the result of a vital and compelling public need.

Trend Toward More Stringent Controls

The fact that tremendous progress in the science of food technology has been made in the comparatively recent past has accelerated the ineluctable trend toward further and more stringent controls. The growth of the world's population has greatly increased the need for greater crop development and the use of pesticides to combat insect infestations and plant disease. Specialized farming, which makes it necessary to ship crops to distant points, together with the need for long storage periods, has provided an impetus for the introduction of various methods of food preservation. The increasing demand for a more abundant food supply has accelerated the growing tendency to utilize synthetics not only to enhance food flavor and appearance, but, more important, to prevent waste and spoilage.

Need for Use of Synthetic Ingredients

At this stage of our civilization, there is a genuine need for the use of many synthetic ingredients, directly and indirectly, in connection with our food supply. Many of the entities directly added to foods have proved to be of substantial value to the consumer and constitute a necessary adjunct to modern civilization. Few would quarrel now with the advisability of enriching various staple foods with certain vitamins and minerals, or with the addition of other substances which enhance the nutritive value of the products in which they are incorporated.

New substances are being introduced into the production, processing, storage, packaging and distribution of food at an ever-increasing rate. There is hardly a food sold in the market place today which has not had some chemicals used on or in it at some stage in its production, processing, packaging, transportation or storage. These foods include those eaten by every family, ranging from staples like bread to such luxury items as the maraschino cherry.

The indirect addition of synthetics to our food supply also raises problems. For example, as we know, cattle are being treated with antibiotic drugs in the control of mastitis, anthrax and other diseases. There is a question of whether the presence of small amounts of antibiotics in food products has an effect on the consumer, and whether some consumers may develop a sensitivity or resistance to these substances.

The rapid strides in the application of science to the production and processing of food, and the tremendous increase in the armamen-

tarium of the medical profession by the production of new drugs, offer great and increasing possibilities for the welfare of mankind. There is no doubt that these vast advances in medicine and food technology have been accompanied by risks. But a certain degree of hazard is inevitable. Many earnest consumer groups and lawmakers may not realize this, but those engaged in the scientific and medical disciplines do. No one can fairly quarrel with the proposition, however, that the risks should be kept to a minimum, and that it is imperative that there be strong governmental controls to achieve this end.

Industries Entitled to Tremendous Credit

The American public may feel justifiably proud of the manner in which the scientists of this country, in conjunction with the food, drug and chemical industries, have attacked the many serious problems which have arisen. The food and drug industries are entitled to tremendous credit for the progress of research in the field of nutrition and in the prevention and treatment of disease. This has resulted in an improvement in the health and nutritional status of millions. Nevertheless, in the type of civilization in which we now live, the ordinary consumer is in no position whatever to judge the quality or fitness of the foods and drugs he is purchasing. In addition, it appears to me that he is entitled to protection against inadvertent mistakes and premature enthusiasms.

As is frequently the situation with social and economic problems, there are varying public policy considerations. Certainly, in the area of food and drugs, the primary motivation is the protection of the consumer's health and purse. But regulation which (although it may add in some respect to the protection of the consumer) is unreasonable or harsh, and increases the cost of the foods and drugs all of us must consume, may seriously hamper research and the appearance on the market of new, better, and even life-saving products.

Further Restrictions Would Not Aid Consuming Public

Congress has attempted to meet the major factor of protection of the consumer by drastic legislation. Yet, despite the passage of the extremely far-reaching Food Additives Amendment, Color Additive Amendments, and the Drug Amendments of 1962, there is a constant demand for further and more restrictive legislation. Those who have dealt extensively with the problems involved and with the amendments to the Federal Food, Drug and Cosmetic Act which have been

enacted, and who have been immersed in the regulations which have been issued under these statutes and have observed their administration and enforcement, are convinced that further controls and restrictions are not warranted. As indicated, they are of the opinion that further restrictions which hamper technological improvements in food production and processing, and research in the medical sciences, would not only not aid the consuming public but definitely act to its detriment.

The 1938 Federal Food, Drug and Cosmetic Act represented, as do many other statutes, a series of compromises, the process of give-and-take which is typical of our democratic system. As enacted, it was not all that its proponents, and was more than its opponents, desired. But that by and large it was a beneficial piece of legislation, and that it definitely was required from the viewpoint of industry and certainly so far as the public was concerned, no reasonable man can dispute. Further and more stringent controls have continuously been created by Congress and, sometimes unhappily, by administration construction.

It is important to realize the bases for the present progressive attitude and broad outlook of the nonmarginal producers and distributors of food and drugs toward this regulatory legislation—their willingness, in fact their alacrity, to accept reasonable regulatory control. The first is that possessed by any decent citizen—the realization that the consuming public is entitled to protection against the knave, the charlatan, the cheat. The second is the knowledge that every intelligent businessman has—that not only is it to his definite advantage to get rid of unfair competition based on economic chicanery and fraud, but that a public confidence in the soundness and honesty of his wares will, as a logical proposition, stimulate their sale.

No social or economic piece of legislation can be effectively enforced unless it is supported, and viewed with some sympathy and understanding, by the responsible members of the regulated industry. This is not a strange phenomenon. If the particular legislation and its administration are completely unreasonable so that it unnecessarily fetters those who are engaged in the industry involved, this in turn adversely affects the consuming public. Further, it is safe to say that, as a fact of life, there will be violations, avoidances and evasions. The reaction to unnecessary and absurd regulation may result in a sense of helplessness and resentment on the part of industry and the belief, wrong though it may be, that it is just necessary to cut a corner and take a risk. But all this is not necessary. Legislation

which is strong (even though perhaps not palatable to industry), and which is firmly, fairly, and efficiently administered but does not go beyond the intent of Congress, in due course frequently benefits industry as well as the consuming public.

Effect of New Drug Provisions

The inclusion in the 1938 Federal Food, Drug and Cosmetic Act of the new drug provisions, caused by the Elixir Sulfanilamide incident, was viewed with horror and dismay by many segments of the drug industry. Yet, years later, an official of one of the larger members of the drug industry said publicly that any official of a drug company who sought to repeal the new drug provisions should have his head examined. The reason for this, it seems to me, is clear. Certainly, the new drug provisions seemed to constitute a further inroad by the government in what used to be called our free enterprise system. In fact, nasty terms such as "licensing" or "approved" were anathema and could not be employed. Peculiar terminology such as "made effective" was used. But these further controls created a greater confidence in the public with respect to the drugs it was purchasing, and this was reflected in the balance sheet.

So far as the larger segments of the drug industry are concerned, there may be the same outcome with respect to the Drug Amendments of 1962. First, there are screams and complaints, some of them well justified. This is occasioned by the breadth of the law, the customary issuance of numerous regulations, some of which appear to go far beyond the scope of what Congress intended (notwithstanding that it is difficult to conceive of the law being much stronger), the sometimes inordinate delays, and the tendency on the part of a few officials to say "no" almost as a reflex-response. But this will pass. And again, the public will be further strengthened in its belief in the safety and therapeutic merit of the drugs it is purchasing. Despite the cries of outrage and expressions of misgivings against the bureaucrats, profits will probably increase. Government officials do not all wear horns (at least not all the time), and the FDA is composed of many reasonable and well-informed people who, of course, put the consumer first but are sympathetic with industry's problems and try to help resolve them.

Fundamental Objectives of Government and Industry Are Similar

Aside from this, it seems clear to me that the fundamental objectives of government and industry in the food and drug areas are by

no means poles apart. Every government official is a consumer. He wants his foods and drugs to be safe and effective; he does not want to pay excessive prices for them, occasioned by unnecessary regulation; he does not wish effective drugs to be kept off the market. And I think it is safe to say that those in industry are also consumers and do not all wear horns, and do not wish to depopulate the country by the manufacture and distribution of lethal drugs. The fact that those in industry wish to make a profit is not (at least as of now) considered to be illegal or even unethical, and is not looked upon with disfavor by every government official.

So far as I am concerned, it is not wishful thinking or starry-eyed optimism to conclude that the ultimate objectives of industry and the government are not necessarily dissimilar. The fundamental rapport which should exist between industry and the government was well expressed recently by the newly appointed Director of the FDA's Bureau of Medicine. He said:

> I can see the pharmaceutical industry's problems and I'll be out to help in solving them. I will be a public servant and will serve both the public and the industry in helping to get new drugs approved. Obviously, there will be differences of opinion, but there is no reason why these should not be ironed out. **[The End]**

POLYUNSATURATED OIL PRODUCTS FACED WITH LEGAL ACTION

The Food and Drug Administration has announced that legal action will be taken if vegetable oil products continue to be misbranded with claims that they are "polyunsaturated" and thus supposedly effective in treating or preventing heart or artery disease.

The announcement was made by George P. Larrick, Commissioner of Food and Drugs, at a meeting of FDA's Public Service Committee, which is composed of representatives of national consumer organizations.

Mr. Larrick told the consumer representatives that FDA's decision to proceed agianst the health claims being made for vegetable oil products was based on the results of a consumer survey on public understanding of current labeling of such products. He said the survey shows that label terms such as "polyunsaturated," "unsaturated," "low in cholesterol," and similar statements mislead many people to believe that these foods will reduce blood cholesterol and thus be effective in treating or preventing heart and artery disease. Other misleading phrases include, "ask your doctor," "better for people's health," "are you concerned about saturated facts," and "better for you because it's made from 100% golden corn oil."

The Commissioner urged the food industry to correct promptly such labeling and promotional practices for oils, fats and related foods which tend to mislead consumers.

Mr. Larrick urged that any promotion of products that purport to be of value for cholesterol reduction be directed solely to the medical profession.—FOOD DRUG COSMETIC LAW REPORTS ¶ 40,124.

How Safe Is Our Food?

By ROBERT S. ROE

This Paper Was Delivered at the Seventy-ninth Annual Convention of the American Association for Health, Physical Education in Washington, D. C., on May 12, 1964. The Author Is Director of the Bureau of Scientific Standards and Evaluation of the Food and Drug Administration.

A SHORT ANSWER to the question constituting the title of this paper would be: our food is very safe. It has been my observation that I and most of my colleagues in the Food and Drug Administration have good appetites and enjoy our meals. We obtain our food from the same sources—that is the usual commercial markets—that other citizens do. We expect that our meals, whether at home or "out" will be safe, nutritious, tasty, and attractive. Usually, we are not disappointed. I have heard it repeatedly asserted by representatives of agriculture, industry, and by health and food officials that the American citizen today enjoys the safest and most nutritious food supply of any people in history. I cannot attest to the accuracy of this claim since my personal experience has been confined largely to the current American diet and does not extend over all periods of history. I shall not stop at this point, however, with that answer. As one associated with an organization responsible for administration of laws, the purpose of which is to insure the safety of our foods, I think I should say something about the problems and the hazards that have brought such laws into being.

The history and content of laws dealing with foods and drugs in this country are very interesting. These laws have been enacted to meet needs arising from scientific and technological developments. The first federal law regulating food and drugs generally was enacted in 1906. The scientific and technological developments during the century preceding 1906 underlaid the industrial revolution of that period. The shift from an agricultural to a predominantly industrial society brought new processes in food production and storage, wider distribution of, and greater dependence upon commercial foods. In enacting the Food and Drugs Act of 1906, the Congress in effect repealed the doctrine of *caveat emptor*—"let the buyer beware"—as ap-

plied to food and drugs. The "play of the market place" was not considered sufficient to insure the purity and integrity of the food supply. In that enactment, Congress asserted the responsibility of the government to require the wholesomeness and the integrity of foods and drugs within its jurisdiction.

It required about a quarter of a century of discussions and debate to bring about enactment of the Food and Drugs Act of 1906. The debates cited many crude debasements and substitutions in commercial foods, such as the substitution of glucose for maple sugar or maple sirup, the watering of milk, the substitution of other fats for butter, and the rank sophistication of spices. Also cited were careless and hazardous uses of preservatives, such as boric acid and formaldehyde.

1938 Law Extended Coverage

Science is not static and technology continued to advance. This first federal law was inadequate. A revision in 1938 significantly extended the coverage. It extended regulation to cosmetics. It improved the requirements with respect to drugs. It made significant advances with respect to foods, providing for the establishment of standards of identity and quality and fill of container, for informative labeling, and for sanitary requirements in manufacturing and storage plants. These new requirements resulted in substantial improvements in sanitation in factories and warehouses that protected foods from contamination by insects, rodents and spoilage organisms. Industry-wide programs brought about many improvements in the production and distribution of certain staple food commodities from farm to factory to storage and distribution points.

Scientific discovery has continued at an increasingly rapid pace. The developments of the past several decades present seemingly overwhelming scientific problems, some of which have far-reaching and significant social and public health consequences. Looking back over the last few years, it is evident that we are in the midst of substantial and significant environmental changes. These have been brought about by the atomic age with its accompanying production of radioactivity in various forms; the many new drugs, such as antibiotics and their wide use, not only in the control of disease in humans, but also in other ways, such as animal growth promoters and disease preventives; the pollution of our rivers and streams from industrial wastes; atmospheric contamination—city smog; the vast array of new chemicals never before in existence, such as pesticide chemicals

for agricultural use, food additives and color additives; and new products, such as plastics used in containers and packaging materials.

Recent Amendments

The 1938 law declared a food adulterated if it contained any added poisonous or deleterious ingredient, unless such addition was necessary in its production or could not be avoided under good manufacturing practices. In such cases, but only in such cases, the law authorized establishment of safe tolerances. This "per se" doctrine prohibiting the unnecessary addition of any toxic substance sounds quite reasonable, but it was found to be inadequate, unscientific, and not capable of effective enforcement. The doctrine assumed that a substance could be classified as poisonous or nonpoisonous in the abstract without reference to quantities, dosage, or time. Furthermore, the burden of proof was borne by the government to show that a substance was toxic or deleterious before its use could be prevented or stopped. Little was known about the toxicity of many of the new chemicals that were being advocated for uses that might place residues in foods. In the last decade, the Congress has enacted several very important and significant amendments to the law. These are: the Pesticide Chemicals Amendment, the Food Additives Amendment, and the Color Additives Amendment.

Burden of Proof Shifts to Industry

The purpose of these amendments, as stated in the enacting clauses, is to insure the adequate safety testing of chemicals employed in or on foods before they are so employed. Safety of consumers is the prime consideration. The old "per se" rule is replaced with authority to establish regulations covering the safe use of these substances, including, where necessary, safe tolerances. The burden of proof is shifted. The proponents of the use of chemicals must establish their safety before use, where formerly the government had been obligated to establish the toxicity before use could be prevented or stopped.

Under the Pesticide Amendment, we have issued regulations establishing about 2,500 tolerances, considering the various tolerance levels and the different crops involved. These involve about 130 different chemical substances. These regulations were established only after our scientists were satisfied that the available scientific data established that residues permitted by the tolerances are, in fact, safe and enforceable. Petitioners are required to submit complete informa-

tion concerning the chemistry of the pesticide substance, the residues that will result from the intended uses, and toxicity data. The latter include long-term feeding tests on experimental animals. We are concerned with the possible chronic effects, rather than any immediate acute toxic results, from the ingestion of the small residues that may remain on food crops. Hence, we require that lifetime feeding studies be done on laboratory animals, such as white rats, and long-term feeding studies on other species, such as dogs. Depending upon the type of chemical involved and the character of the toxic responses, other studies and investigations also may be required. Similarly, in the case of food additives, completed information is required concerning the composition and identity of the additives, the chemistry, the residues that may be expected from the intended uses, and the possible toxicity.

Petitions asking tolerances for residues of pesticide chemicals are reviewed and evaluated by our scientists only after the Department of Agriculture has certified that the pesticide chemical would be useful and effective for the purposes intended in agriculture. We then grant a tolerance no larger than is necessary to accomplish the intended purpose, and we do not grant a tolerance at all, unless the tolerance established is safe. In the case of food additives, we are interested not only in additives that are placed directly into food for some purpose, as a preservative, an emulsifier, a thickener or for some other desirable purpose, but also indirect and unintended additives. These may represent chemicals used in packaging materials or in the utensils, and conveyors employed in manufacturing plants that might migrate to food on contact. Regulations for food additives are established only after evidence has shown that the additive accomplishes the intended effect, is safe, and does not serve to conceal inferiority or damage, or otherwise result in deception.

With respect to the tolerances which have been established for pesticide chemicals, I should like to point out that the tolerance levels have been adjudged safe assuming that such levels were present on all of the crops covered by the regulation. For instance, tolerances at seven parts per million have been established for DDT on over 40 different fruits and vegetables. This has been adjudged safe, assuming that all of these fruits and vegetables bore residues at that level. Actually they do not. Very seldom do we encounter residues above two or three parts per million on individual shipments of particular crops.

Occasionally you may hear that some food shipment has been taken off the market because it contains nonpermitted pesticides or residues that exceed the legal tolerances. This simply means that the law is working as it was intended—to protect the consumer. Last year our laboratories analyzed over 25,000 samples of food commodities for pesticides. There were 40 seizures of shipments that contained illegal residues.

Diet Studies Check Pesticide Residues

For the past several years, we have been checking the residues in a total diet study to determine just how much pesticide chemical residues are likely being consumed in the usual diet. These studies have been carried out in several locations throughout the country utilizing a diet that might be consumed by a teen-age boy. Periodically, a two-week supply of foods—meats, vegetables, fruits, milk and dairy products, even soda pop—is purchased at various markets and prepared for the table in the usual manner, including cooking.

The pesticide residues remaining in food as prepared for the table are indeed very small. They are minute and insignificant so far as any health hazard is concerned. We do find traces in measurable amounts of some of the chlorinated hydrocarbons, such as DDT, but these are in fractions of a part per million. These studies have satisfied us that the food supply in general is not a source of hazardous residues of pesticide chemicals. We are planning to continue and expand this type of surveillance check with respect to all types of pesticide chemicals and probably with respect to some types of food additives. This study originally was undertaken to check possible development of radioactivity in our food supply as a result of fallout. This check also is being continued.

We are also examining our total diet samples for nutrients, such as vitamins, as a check on the nutritive values in our currently distributed foods. Much has been said by self-styled nutritionists and promoters of special dietary foods as to nutritive deficiencies in our food resulting from soil depletion, overrefinement, and destruction in food processing. We found no deficiencies in vitamins in our total diet study. We were not surprised at this finding, but it does serve to confirm the fact that a well-balanced diet, which is generally available to most of our population, is nutritionally adequate, and there is no need for expensive dietary supplements.

Conclusion

No one can guarantee absolute safety in our food supply. Food poisonings are reported every year, particularly at picnic time in the summers. These incidental poisonings usually result from mishandling food, careless handling, or from inadequate sanitation. A number of recent food poisonings (botulinus) have been traced to commercial foods, and here, too, investigation reveals a breakdown in adequate controls or mishandling in distribution. Such incidents are the exceptions, rather than the norm. Nevertheless, the complexity of our present-day civilization, the continued advances in science and technological applications in agriculture and industry make it more essential than ever that up-to-date, well-designed and adequately enforced regulatory laws continue with respect to foods and drugs. Our food supply will continue to be safe so long as producers, manufacturers, distributors and government regulatory agencies remain alert and maintain sound scientific controls. **[The End]**

FDA MEDICAL DIRECTOR ADVISES PHYSICIANS TO UTILIZE DRUG INFORMATION

Physicians have a duty to their patients to inform themselves fully about the medicine they prescribe, Joseph F. Sadusk, Jr., M.D., Medical Director of the Food and Drug Administration, Department of Health, Education, and Welfare, told the American Medical Association yesterday.

Dr. Sadusk urged physicians to read fully the labeling of drugs as well as various publications covering indications for use, warnings and contraindications for use.

"Good and potent drugs continue to appear for your use," he told the nation's doctors at the AMA's annual convention in San Francisco, California. "But as the potency of these drugs increases, so generally does their complexity and their potentiality for harm. Consequently, it is your duty to fully inform yourself of the composition, mode of action, efficacy, and potential toxicity of these agents before you embark upon their use. This information is readily available to you in all package inserts, in direct mailing pieces, and in brief summary form even in the prescription drug advertising. You owe a duty to your patient to use this information."

Dr. Sadusk, who last spring left his position as Professor of Preventive Medicine and Community Health at the George Washington School of Medicine to become FDA's Medical Director, addressed the joint meeting of the AMA's sections on Autoimmune Diseases, Experimental Medicine and Therapeutics, Internal Medicine, Pathology and Physiology, and Preventive Medicine.

Dr. Sadusk's address was the first in recent years to the national meeting of the AMA by an FDA Medical Director. The Agency said it is part of an increased emphasis upon communication between FDA and the nation's medical and scientific community.

The Scientists' Forum

The Food Chemicals Codex Off the Press

By BERNARD L. OSER

President and Director, Food and Drug Research Laboratories, Inc.

The Following Is a Report on the Food Chemicals Codex by Dr. Oser, Scientific Editor of This Magazine.

IN THE NOVEMBER 1957 ISSUE of FOOD DRUG COSMETIC LAW JOURNAL the writer raised his voice in support of the establishment of a compendium of definitions and standards of purity of food chemicals. It was suggested that the compendium be called a Bromatopeia in analogy with the Pharmacopeia of drugs. Notwithstanding its etymological soundness, the proposed designation met with almost universal rejection (not surprising in this age of anti-intellectualism) but the idea persisted, and has now reached the stage of consummation. We are happy to report that the curtain has been raised on the first installment of the Food Chemicals Codex, a project sponsored by the Food Protection Committee of the National Academy of Sciences-National Research Council.

In the article referred to, the writer stated:

> Official compendia have been developed and are revised through the cooperate efforts of academic, governmental, medical and industrial scientists who furnish up-to-date information relating to pharmaceutical products in current use. It would seem that a nongovernmental agency similar to the United States Pharmacopeial Convention, Inc., could be organized to undertake a compendium of food additives, enlisting for this purpose the collaboration of specialists in the various fields concerned, including government scientists.

The Food Chemicals Codex is the result of precisely this sort of collaborative effort, carried out under the direction of Dr. Justin L. Powers, formerly Director of Revision of the National Formulary. With the technical assistance of a scientific advisory panel and with financial support derived in part from a $50,000 annual grant from the United States Public Health Service and in part from industrial

contributions (which it is hoped will continue), the Codex staff has issued in astonishingly short time, Part I of what bids fair to be the definitive compilation of standards for food additives in use in the United States. That it will ultimately attain the official status enjoyed by the United States Pharmacopeia (and other drug compendia) is devoutly to be wished. (Hopefully this should take less time than the United States Pharmacopeia which first appeared more than 80 years before it achieved official recognition in the Food and Drugs Act of 1906.)

The Food and Drug Administration has clarified its view of "food grade" chemicals in the following terms, which also emphasize the importance of an official compendium.

> Specifications for a substance must be adequate to assure that the substance is safe and suitable for the food purpose intended. Obviously, a standard of purity appropriate for a chemical such as calcium carbonate used in the manufacture of food packaging grade paper, where only traces of the calcium carbonate and its impurities might indirectly be added to food, would not necessarily be adequate for calcium carbonate added directly to food at a level of 0.3% for the purpose of enriching it. Moreover, a standard of purity for a substance which is quite satisfactory when it is used as a drug may not necessarily be adequate for it when used as a food additive. For example, current specifications for USP mineral oil, oleic acid, and stearic acid, are not deemed adequate for assuring "food grade" because they do not satisfactorily limit certain toxic impurities which may be present, and specifications for USP sodium bisulfate are not deemed adequate because they do not limit selenium, a common toxic impurity of this compound. For "food grade" sodium bisulfite we have tentatively supplemented the specifications of the USP with a specification limiting Se to 30 ppm based on the sulfur dioxide content. Moreover, USP and NF specifications do not always limit the three common toxic impurities, arsenic, lead, and total heavy metals. . . .
>
> *Until a compendium prescribing definitions and standards of identity and purity for food additives is compiled and officially adopted,* or until specifications for "food grade" chemicals are established by regulation, we propose to follow the policy outlined above.[1] (Italics supplied.)

Part I of the Food Chemicals Codex is the first of eight or ten sections which will be issued in loose-leaf form. It comprises 118 pages of what upon completion, probably in 1966, will be a 700- or 800-page compendium. Starting with a prefatory discussion of the organization of the Codex, it continues with the general provisions applicable to standards, tests and assays. This is followed by 25 monographs containing, for each chemical, its common and chemical names and formula, description, identification tests, specifications for purity, pertinent tests and assays, packaging and storing recommendations, and examples of its functional role in foods. This install-

[1] From an address by L. L. Ramsey, Division of Food, Bureau of Biological and Physical Sciences, Food and Drug Administration before the American Chemican Society, September 1960.

ment concludes with major sections on general tests, apparatus, solutions, and indicators, and finally an Index.

Subsequent installments are expected to appear at approximately 4-month intervals and will eventually cover about 600 food grade chemicals. Subscriptions for the complete Codex in loose-leaf form including a durable binder are available at $25.

A similar project toward establishing standards for the identity and purity of food additives has been in progress for the past six years under the joint sponsorship of the Food and Agriculture Organization and World Health Organization. Already published are two volumes entitled Specifications for Identity and Purity of Food Additives, namely, Vol. 1 covering 31 monographs on Antimicrobial Preservatives and Antioxidants and a second volume covering 41 Food Colors. In process is a series of monographs on emulsifiers, stabilizers, bleaching and maturing agents. It is interesting to note that Dr. Powers was an observer at the meeting of the Joint Expert Committee in February 1963 which developed the latter specifications. Exchange of basic technical information on standards for the purity and safety of food chemicals should serve to promote international agreement and thus facilitate commerce in food products.

The Codex Alimentarius currently being developed under the auspices of FAO and WHO is intended to set up definitions and standards for foods. The Codex Alimentarius Commission is composed of representatives of the participating governments from which it derives its financial support. Whether and to what extent the recommendations of the Codex Alimentarius will be adopted by the European Economic Community remains to be seen.

Our own Food Chemicals Codex represents a genuine forward step, not in conflict with any existing regulations and not encumbered by conflicting national interests, all of which augurs well for its future official status. Dr. Powers, his staff and his collaborators, are to be congratulated on this achievement. [The End]

ZERO TOLERANCES FOR PESTICIDES TO BE STUDIED

Due to improving test methods and the danger that a product showing no pesticide residue today may be found to contain a residue by a new test method, the National Academy of Sciences, in response to a request of the Secretary of Health, Education and Welfare, and the Department of Agriculture, has undertaken the study of this zero tolerance problem and has indicated that it will make recommendations by the end of 1964, the Food and Drug Administration has announced.—Food Drug Cosmetic Law Reports ¶ 60,058.

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

June Food Seizures Report.—Seizures during May totaled 249 actions to remove from the market products charged to be adulterated or misbranded. The total included 45 seizures of food products: seven vitamins and minerals; 25 drugs; 13 types of medical devices; one cosmetic; and 158 seizures of two hazardous household substances.

More than two million pounds of food were seized in 45 actions. Thirty-one actions charging contamination, spoilage and insanitary handling accounted for 1,562,779 pounds. Charges of economic violations resulted in 43,015 pounds of food products being removed from distribution channels. Four actions charging contamination with poisonous and deleterious substances were brought against 410,140 pounds of food.

Drug and Device Seizures.—Twenty-five seizures of drugs included six actions on charges that the product is a new drug not approved for safety and effectiveness. Actions against medical devices for false and misleading claims accounted for seizures of 15 devices during May. Among those seized was a device manufactured and shipped by a firm in Salt Lake City, Utah. The device was claimed effective for treating arthritis, whooping cough, asthma, ulcers, kidney infections, tumors, hemorrhoids, paralysis, and cataracts. The device is a large wooden cabinet containing electrical circuitry for the production of high voltage, high frequency, low intensity currents to be applied to the body through a variety of glass tubes and metal electrodes. Seized with the device was a 23-page booklet describing the device.

Hazardous Substances.—Seizures of hazardous substances totaled 158 with all but one being against a water repellent on charges that the product failed to bear consumer protection information required by the Federal Hazardous Substances Labeling Act. One action was brought against a liquid preservative on the same charge.

Voluntary Actions by Industry.—The food industry voluntarily diverted 36,324,800 pounds of unfit food from consumer marketing channels in 123 separate actions during May. Part of the food was diverted to nonhuman use, while the remainder had to be destroyed. Included in the total were 3,054,600 pounds of moldy and rancid cocoa beans; 129,000 pounds of moldy, insect-contaminated ground chilies; 61,700 pounds of corn contaminated with red dye; 121,800 pounds of rodent-contaminated wheat; 32,460,000 pounds of rancid and filthy safflower seed; 28,800 pounds of fire-damaged carrots; and, 29,200 pounds of rodent-contaminated wheat.

Drug manufacturers voluntarily destroyed 65 lots of violative drugs and devices which would have sold for $708,500. Included were fire-damaged prescription drugs; a therapeutic multivitamin product in which niacin was substituted for niacinamide; aspirin mixed with foreign drugs; and miscellaneous drugs which had become useless.

Detailed Guidance on
Drug and Cosmetic Regulation

Food Drug Cosmetic Law Reports

Drugs-Cosmetics Edition

Drug and cosmetic executives and their counsel must keep posted on fast-changing federal and state rules covering drugs, cosmetics and therapeutic devices—while keeping on top of the many technological and processing advances that prompt many changes in the rules. Because of this never-ending battle, many of them welcome the help CCH's Food Drug Cosmetic Law Reports—DRUGS • COSMETICS Edition offers.

Subscription for the REPORTS provides coverage of the application and interpretation of the Federal Food, Drug, and Cosmetic Act, as administered through the Food and Drug Administration, plus additional valuable help in working with related federal and state requirements.

1. *Weekly Reporting to Keep You Posted.* Today's complex drug, cosmetic and device control problems and fast-changing rules make essential "instant" coverage of new laws and amendments; FDA regulations, rulings and releases; court decisions; color additives petitions.

2. *Three "Catch-Up" Volumes Bring You TODAY's Rules.* Included at no extra cost, these Volumes bring together currently effective rules, with emphasis on such features as:

   INDEX TO SUBSTANCES, listing the thousands of substances dealt with in the federal laws, FDA regulations, and food or color additives petitions, with multiple listings for compounds.

   NEW DRUGS requirements, including safety clearance procedures.

   FEDERAL PURITY and LABELING requirements and prohibitions for drugs, cosmetics, and therapeutic devices.

   COURT DECISIONS interpreting drug and cosmetic law issues.

   STATE PURITY, PACKAGING and LABELING requirements.

   FEDERAL HAZARDOUS SUBSTANCES LABELING requirements.

   FORMS prescribed under the Act.

   COLOR ADDITIVES and PESTICIDE rules and petitions.

   ANTIBIOTICS TESTING and CERTIFICATION requirements.

Subscribe for Drug and Cosmetic Regulation Reporting Now

Just your OK on the attached post-free Card starts everything your way now. Your volumes will come to you immediately, followed by weekly reporting to keep you up to date on new developments. Your satisfaction is guaranteed.

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS of TOPICAL LAW REPORTS

NEW YORK 17
420 LEXINGTON AVE

CHICAGO 46
4025 W. PETERSON AVE

WASHINGTON 4
425 13TH STREET, N. W.

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4025 W. PETERSON AVE. CHICAGO 46, ILL.
RETURN REQUESTED

SECOND CLASS POSTAGE
PAID AT CHICAGO, ILLINOIS

A COMMERCE CLEARING HOUSE PUBLICATION