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Food Drug Cosmetic Law JOURNAL

Papers Presented at the 1963 Joint National Conference of The Food and Drug Administration and The Food Law Institute, Inc.

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

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

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Table of Contents . . . December, 1963

VOLUME 18 NUMBER 12

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

The 1963 Joint National Conference of the Food and Drug Administration and the Food Law Institute, Inc., was held on December 2, 1963 in the auditorium of the United States Department of Health, Education and Welfare, Washington, D. C. Its purpose was to observe the 25th anniversary of the enactment of the Federal Food, Drug and Cosmetic Act and to review regulatory and scientific problems under that act and related legislation. This issue of the JOURNAL contains the papers which were presented at the morning session of the conference, along with two papers from the afternoon session.

Frederick Brown Harris, D. D., Chaplain of the United States Senate, delivered the invocation. Welcoming statements were made by the Secretary of Health, Education and Welfare, *Anthony J. Celebrezze,* reported at page 668, and *William T. Brady,* Chairman of the Board of Trustees of the Food Law Institute.

Winton B. Rankin, Assistant Commissioner of Food and Drugs, served as moderator in a discussion on "Accomplishments, Responsibilities and Opportunities in the Food and Drug Field." He advocated additional factory inspection authority for the FDA in his comments which begin on page 673. The Deputy Commissioner of Food and Drugs, *John L. Harvey,* considered the FDA's responsibilities and the opportunities for cooperation in discharging these responsibilities, in remarks which appear on page 675. The need for education of responsible industry personnel was discussed by *Paul S. Willis,* president of the Grocery Manufacturers of America, Inc., in an article appearing on page 684. "The Food Industry and Free Enterprise" was the topic considered by *Robert L. Gibson, Jr.,* president of Libby, McNeill & Libby, which begins on page 687. The president of Winthrop Laboratories, *Dr. Theodore G. Klump,* commented on the powers of FDA in an article beginning on page 695. Factory inspection was discussed by a Washington, D. C. attorney, *Edward Brown Williams,* in a paper starting on page 705.

"Scientific Bases for Food Laws" is the title of the paper presented by *Paul R. Cannon* of the University of Chicago, which begins on page 712. On page 718 is an article by *Fredus N. Peters,* Food and Nutrition Board of the National Academy of Sciences, which explores scientific bases for food legislation and regulation.

An index appears at page 724 of all the 1963 articles, according to author and title. Articles are also listed under appropriate general subject headings.

Vol. 18, No. 12 December, 1963

Food·Drug·Cosmetic Law
Journal

Welcoming Address

By ANTHONY J. CELEBREZZE

Mr. Celebrezze, the Secretary of the Department of Health, Education and Welfare, Presented These Introductory Remarks at the Annual Joint Conference of the Food and Drug Administration and the Food Law Institute, Inc., on December 2, 1963.

ON THIS TWENTY-FIFTH ANNIVERSARY of the Federal Food, Drug and Cosmetic Act, it is appropriate to note that major food and drug reform in this country has followed a characteristic pattern. There is a recognized need for improvement. There is a crisis with a tragedy occurring or narrowly averted. A new law is passed and regulations developed and issued. Those whose industries are regulated fear they cannot live under the new rules. They find that they can and that, in the long run, everyone benefits. Responsible manufacturers benefit. Responsible retailers benefit. Consumers benefit.

This was true of the original Pure Food and Drug Law of 1906. This was true of the 1938 law, which was passed after five years of debate and only after over 100 people had died from use of a new drug which had not been properly tested. It is true of the Kefauver-Harris Amendments of 1962, passage of which was spurred by the thalidomide disaster, and implementation of which has brought the not unexpected industry reaction.

There have been fears that the new law and the regulations issued within the past year would stifle research, dry up the development of new drugs in this country, and drive small firms out of business.

But careful appraisal of the new requirements as they relate to the development and testing of new drugs reveals little or no basis for these fears. The new requirements of law and regulation are

basically the same requirements responsible investigators have recognized and accepted for many years.

These provisions are designed to correct grave abuses that developed under the older procedures governing clinical testing of new drugs. They are designed to protect patients, clinical investigators and responsible manufacturers. In short they will protect society in an area where added safeguards are solely required.

Now I do not wish to imply that we are without problems. There were many difficult questions presented by the new procedures. Some of them have been answered in whole or in part. Others are still under study and their resolution will require more time. We are in a period of transition, and the Food and Drug Administration stands ready to work with all interested persons in seeking better methods of reaching thoroughly workable and satisfactory solutions to any remaining problems.

The drug area is not the only one that deserves our careful attention and joint efforts. The tremendous scientific and technological advances of recent years have touched and changed all aspects of life including: the food we eat, the therapeutic devices and cosmetics we use, and the myriad household aids that often present unexpected hazards in our homes.

Effective regulatory control of these commodities—and drugs—is essential to the health and well-being of the American people. This has prompted the development in the FDA of our department of a regulatory program of broad reach and great depth.

FDA's Reorganization

The Food and Drug Administration has a vital job to do—one that grows in size and complexity as our society itself grows. To keep up with its responsibilities, the FDA must change—as it has changed and is now changing, as a result of both legislative and administrative action.

Since January 1960, for example, its appropriation and its staff have more than doubled. Its quarters have been enlarged. Its scientific stature is now being upgraded, and the agency is in the process of a major reorganization to improve its capabilities to meet the challenges of today and tomorrow.

Some of the broad thinking back of the organization changes may be of particular interest to you.

The Bureau of Medicine was reorganized last December so that it could handle better both its increased responsibilities under the old law and the tremendous new responsibilities resulting from the enactment of the new one.

Among other things, we established a special branch to deal with notices submitted in connection with investigations of new drugs.

Later FDA formed a special advisory committee of experts to give counsel in the investigational new drug area. Other organizational changes were effected so that the major workloads that had been identified could be handled more expeditiously by specially designated personnel.

This increased emphasis on the scientific aspect of FDA's operations is being carried through in the most recent reorganization by the establishment of a new post of Associate Commissioner and by the establishment of two scientific bureaus to replace the present Bureau of Biological and Physical Sciences.

Scientist Will Fill Assistant Commissioner Post

The Assistant Commissioner post will be filled by a scientist who will bring to the top echelons of FDA current thinking from the scientific community and who will assist in providing closer liaison between the agency and the numerous places outside whose research activities have a bearing upon consumer protection in the food and drug area.

Additionally, we are taking measures to give greater emphasis to methods that can be employed to bring about more widespread voluntary compliance with the law. All of us would agree, I imagine, that the ideal situation would be one in which the government never has to apply sanctions because everyone recognizes and meets his obligations.

Specific Rules Established in Advance Aid Industry

We are not likely to reach this happy state of affairs in our lifetime. We are, however, working in that direction. FDA has shifted in recent years in accordance with changes in substantive law toward the increased establishment of specific rules in advance which guide industry toward law compliance. These rules or regulations have been quite helpful. They make it possible for the responsible individual to determine with greater assurance just what he must do to meet the federal requirements.

But we need more. We need a broad program of education which encourages voluntary compliance. We need a broad program of education for the consumer so that he will know what to expect from the FDA and how to use the label and other information with regard to foods and drugs to his best advantage.

So we are establishing a Bureau of Education and Voluntary Compliance to meet these needs. It will initiate programs aimed at informing the public, as well as industry. One result of this new activity will be to make it even easier for the regulated industries to determine how to conduct their activities in complete harmony with the law.

National Advisory Food and Drug Council Formed

To keep in closer touch with the needs of society and with the wishes of consumers, I have authorized the formation of a National Advisory Food and Drug Council under the chairmanship of George P. Larrick. The council will draw its members from the fields of science, industry, government, labor, law and consumer activities. These citizens will advise the FDA of national needs and the effectiveness of program policies.

Another area in which there will be greatly increased emphasis is not reflected in the reorganization plan itself. We want to encourage state and local governments to undertake increasing responsibility for consumer protection in their own areas. Some states are already doing this to some degree, but there is a need for development of a far more effective working relationship in which state and local governments assume fully the responsibilities for consumer protection they can best perform and the federal government devotes its resources to those activities which can be more efficiently performed by one national agency rather than by 50 state agencies. For example, there would seem to be no need for each of the 50 states to maintain the staffs of highly trained scientific and technical personnel required to establish safe pesticide tolerances or to approve new drugs for marketing. The federal government should continue to exercise the major responsibility in this area.

But there is a tremendous need for increased state operation and we intend to press forward vigorously to help the states prepare themselves to operate more effectively in these areas.

Looking back over the years, it is clear that the responsibility for consumer protection has expanded at all levels of government and

within industry itself. The complex technology involved in the production and processing of foods, drugs and cosmetics—their greater use—their potential hazards—all these have contributed to an unprecedented public dependency on the judgments and actions of responsible industries and on the safeguards provided by law.

Conclusion

In recounting the historical highlights of food and drug legislation, it is clear that the circumstances that exist today were undreamed of in 1900 or indeed a quarter of a century ago—in 1938—when the National Pure Food and Drug Law was given its first complete overhaul.

By the same token, we can expect in the years ahead to see new circumstances and new problems which we must be prepared to meet.

We hold in our hands—government and industry—the faith and trust *and* the well-being of millions of individuals.

Let us keep that trust.

Let us keep that trust by continuing to work together, so that all may reach our common goals with full regard for the rights of consumers, with the minimum restraint upon industry, and with a maximum of understanding on all sides.

The Food Law Institute is to be commended for the contributions it is making to the free exchange of information and to the understanding and effective administration of our laws.

I wish you continued success in the years ahead. [The End]

MISBRANDED DIETARY SUPPLEMENTS

Seizures were instituted against three dietary supplements which were charged misbranded. Two of these products failed to bear on their labeling the information required by FDA regulations. One of these and a third product were promoted by false and misleading claims. The three products were:

A product that implied that it is effective for developing strong, beautiful fingernails, and is of significant value as a special dietary supplement by reason of its high super-rich protein content in an amount which is low in calories;

A tea and tablets which implied that they are effective as a treatment for asthma and all bronchial complaints, heart and blood conditions, anemia, rheumatoid arthritis, and kindred complaints in all cases of malnutrition; and

A dietary supplement which implied that it is of significant value as a special dietary supplement by reason of its pollen content.

Inspection Authority

By WINTON B. RANKIN

The Author Is Assistant Commissioner, Food and Drug Administration, Department of Health, Education and Welfare.

THE FEDERAL FOOD AND DRUG INSPECTOR now has authority to make a complete inspection when he is in a factory producing prescription drugs. He can inspect records, files, papers, processes, controls and facilities. Certain records are excluded because they do not need to be inspected to determine the legality of a firm's operation from the standpoint of the food and drug laws.

Why was this expanded inspection authority granted in the Kefauver-Harris Drug Amendments of 1962? Because: bad drugs can kill you; present law and facilities only permit occasional spot checks through factory inspection—we do not even get into the drug factory once a year on the average; thus, to draw sound conclusions about the manufacturing operations conducted during almost all the time the firm operates, the inspector must look at manufacturing, control and other records.

The federal inspector does not have the authority to make a complete inspection in a food producing plant. One wonders why. Is food something that is inherently safe as compared with drugs which are inherently toxic? No. Bad food can kill you just as dead as bad drugs. Within recent months there have been a number of deaths from canned and smoked food that developed botulinus toxin.

Is the problem solely one of good sanitation and adequate processing to destroy or retard the growth of bacteria? No. Some of the pesticides and food additives now being used in food handling and production are among the most potent poisons known. Under amendments enacted within the past decade, the government is required to allow these poisons to be used when someone requests permission to use them and shows that a regulation can be written setting forth reasonable and safe conditions for their use. Thus, the marvelous scientific and technological developments of recent years can be utilized more readily for the benefit of our society. But there should

be provision for determining, when the inspector is in the factory, whether the rule was adhered to when he was not present.

Or is this picture too dark? Can we depend upon all food manufacturers to abide by the pure food rules without complete factory inspections? I am happy to say that we can depend on most of them. But not all. The record since the first national Pure Food and Drug law was enacted over 50 years ago shows that over the years there have been some firms that endanger health because they are reckless, irresponsible or deliberate.

Do inspectors get into food factories often enough to make complete inspections, including inspections of pertinent records unnecessary? They do not. On the average we do not inspect a food factory even once a year. We inspect about once every four years.

For the public to be given adequate protection, it is necessary, in addition to greatly increasing the rate of inspection, to let the inspector make a full inspection when he is in the food producing factory. He must have access to complete and accurate information about such things as: manufacturing processes; manufacturing controls; laboratory controls; conditions of storage; and coding and distribution of finished products.

The arguments we have heard against complete inspections do not stand up upon careful examination. And if FDA is to be fully successful in assisting industry to achieve voluntary law compliance, it must be able to determine what needs to be changed to meet the requirements.

Adequate inspections of factories producing nonprescription drugs, therapeutic devices and cosmetics are also essential to proper safeguarding of those who consume or use these commodities. Specific, dramatic examples of need can be cited, but such recitation is not required at this time.

The President proposed to the last Congress an amendment of the Food, Drug and Cosmetic Act that would permit proper inspections of all factories within the jurisdiction of the Act. But only prescription drugs were covered by the inspection amendment that was enacted.

Our Department has proposed legislation now before the Congress, which would remedy the situation with regard to other manufacturing establishments. We expect to continue to call the attention of our Department to the very serious gap in the inspection provision of the law until such time as it is closed. **[The End]**

Accomplishments, Responsibilities and Opportunities in the Food and Drug Field

By JOHN L. HARVEY

The Author Is Deputy Commissioner of Food and Drugs, Department of Health, Education and Welfare.

IT IS A PLEASURE for me to add the welcome of the Food and Drug Administration to that of the Secretary as we open another joint Food and Drug Administration-Food Law Institute Conference. Before he left on an out-of-the-country trip, Commissioner Larrick asked me to convey to you his sincere regrets for not being able to attend this meeting.

In this 25th anniversary year of the enactment of the Federal Food, Drug and Cosmetic Act, it is timely to consider the FDA's responsibilities and the opportunities for cooperation in discharging these responsibilities.

The heavy responsibilities imposed on the FDA by the 1938 law have increased dramatically due to the amendments enacted since that time. The major changes since 1938 have been the antibiotic and insulin certification amendments, the Durham-Humphrey Amendment, the factory inspection amendment of 1953, the Pesticide Chemicals Amendment, the Food Additives Amendment, the Color Additive Amendments and the Kefauver-Harris Drug Amendments. Several of these represent significant advances in the food and drug field. However, most of them came after serious defects in the 1938 law had been revealed by our inability to cope with existing problems under existing law.

FDA Needs Recognized in 1957

I'm sure most of you are aware that the FDA has not always had all of the resources necessary to do its job as completely as everyone would wish. During the first half of this century, when the food,

drug and cosmetic industries were in the midst of a technological revolution, FDA grew at a snail's pace. For instance, from 1938 through 1957 our staff hardly increased at all; in 1955 the total staff numbered 829 as compared to 823 10 years before in 1945. The same is true in terms of our appropriations for this period. Between 1938 and 1957 FDA's budget stayed relatively static, despite increasing costs for personnel, equipment and facilities. In 1957—a half century after enactment of the original law—our needs were more fully recognized and essential resources began to be provided by the Congress in more adequate fashion. This change was largely the result of a study made by a Citizens Advisory Committee in 1955, a distinguished group of eminent citizens including the former president of the Food Law Institute as well as others associated with your industries.

Increase and Shift of Population Great Influence

Meanwhile, tremendous influences were developing, increasing the things we had to do. The total United States population grew by 31 million between 1938 and 1955. In addition to the effect that sheer numbers of consumers have on FDA operations and programs, the Agency is also affected by the way the population is distributed. In this connection it is well to note two important trends that have accompanied our population growth over the past several decades. One of these has been the phenomenal shift from farms to cities. This has had a direct effect on FDA's job, because city dwellers are far more dependent on mass-produced foods than are our citizens who live on farms. Most of the technological developments for the preservation, packing, and distribution of foods, for example, have been stimulated by the industry's need to provide for a fast growing United States urban population. Whereas our farm population was 31 million in 1938, it is 16 million today; and whereas our urban population was 99 million in 1938, it is 172 million today.

The other trend that has characterized our population explosion has been the growing segment made up of citizens 65 and older which increased from 8.4 million in 1928 to 17 million today. These older consumers need more special foods and more drugs—many of them used for long periods—than the average adult population.

Our Gross National Product has grown from $90 billion in 1938 to an estimated $575 billion in 1963. At the same time that the GNP has been growing so has personal consumption expenditures for foods, drugs and cosmetics. This growing economy and this more affluent

population have led to a larger number and variety of products to please an even greater diversity of tastes and demands. Without a doubt, history has never recorded a time when so many people had available to them so many products. All this adds directly to FDA's work load.

A look at our vast supermarkets with their thousands of different products and annual sales of more than twice the value of all the gold in Fort Knox shows in another way what has been happening. Numerically, supermarkets have increased from 6,175 in 1940 to well over 24,000 today.

Technological Advances Add to FDA's Work Load

The third major factor that has contributed to FDA's work load and responsibilities during the past years has been the technological advances made by this country. During the five-year period from 1957 to 1962 the nation's industries producing foods, drugs and therapeutic devices more than doubled their outlays for research and development of new products. This reflects the growing emphasis being placed on scientific research since the end of World War II. Research and development add directly to FDA's job because science, advanced technology and automation: (1) increase the production of foods, drugs, and cosmetics; (2) develop new methods of production and distribution that require new enforcement techniques; and (3) produce new and complex products, such as more sophisticated drugs, new food additives and color additives, increasingly toxic pesticides, and an even greater variety of convenience foods. While industry was spending from $155 million in 1957 to an estimated $375 million in 1963 on research to develop new products, FDA's appropriations for research to protect consumers ranged from $1.2 million in 1957 to $4.3 million in 1963.

Another area presenting more and more serious problems to consumers is that of foods, and here again, FDA has a tremendous work load. For example, there are about 88,500 interstate establishments that produce, process, package, distribute and store foods. Each is subject to FDA inspection, and in 1963 we estimate approximately 20,300 of them were inspected. At this rate, FDA can inspect each of the 88,500 establishments on the average of once every 4.3 years.

Growing Use of Chemical Food Additives

One major trend that has complicated the food picture has been the growing use of chemical food additives. There are today an estimated 2,200 chemicals used by 73,000 food establishments that fall under FDA's jurisdiction. These additives which are used as coloring agents, preservatives, emulsifiers, and for a host of other purposes are essential to the production of our modern convenient foods. FDA must determine how much of any given chemical can be present in any given food product without endangering health.

The food problem that most consumers are very much aware of at this time involves pesticides. Annually, some 600 million pounds of pesticides are used by over 5,000,000 agricultural employees on every imaginable crop grown in the United States, and we estimate that each year there are approximately 2.5 million interstate shipments of raw fruits and vegetables that have been treated at some time or other with an agricultural chemical. We sampled and analyzed over 25,000 shipments or one per cent last fiscal year. This year we hope to collect approximately the same number of samples but to subject them to more extensive analyses. The results of these two years of study will be analyzed to determine with greater accuracy what steps must be taken to provide sound consumer protection in this area. This sampling program is being supplemented by more visits to producing areas and by research to learn more about the effects of various pesticides when ingested as residues in or on foods.

While chemical additives and pesticides, captivate the imagination, we should not for a moment forget the immense task FDA has of protecting consumers against filthy, unsanitary, and harmful foods, and from the unscrupulous fringe that is to be found in any walk of life who try to short-change the American public by deceptive packaging, misleading labeling, and the like.

Responsibilities in Drug Area

In the drug area we have tremendous responsibilities and work loads which fall essentially into four broad areas:

(1) Premarketing control of clinical investigations of new drugs and proof of safety and effectiveness of new drugs. This is handled largely in Washington, though we are beginning to utilize field assistance to a greater extent.

(2) General control of the purity, potency, labeling and promotion of drugs. This is accomplished through inspections, sample collections and examinations, education and consultation.

(3) Attempts to curb illegal sales of prescription drugs.

(4) Work directed against quackery.

The speed with which the drug picture changes is well illustrated by the estimate that 90 per cent of the prescriptions filled today could not have been filled 15 years ago because the drugs had not yet been marketed. In addition the growth of the drug industry is indicated by the extremely sharp increase in consumer spending for prescriptions. This has grown from $150 million in 1940 to approximately $2.2 billion today.

Work processes themselves have become increasingly complex. This arises because the laws FDA administers require demanding procedures, such as the processing of petitions, the establishment of tolerances, the issuance of regulations, and the conduct of hearings; second, because the nature of our work demands high knowledge of and dependence upon scientific technology, medicine, law, and other complex disciplines. In addition, we recognize the need to regulate industry fairly and in a manner permitting the maximum amount of technical and economic progress consistent with the public's well-being.

Data and Advice Obtained from Experts

In deciding whether to approve or disapprove a given proposal, FDA generally reaches beyond its own staff to obtain data and frequently to obtain advice. Industry itself provides much of the basic information that supports a proposal. FDA also depends heavily upon other units of government, such as the Public Health Service of our own Department, the Department of Agriculture, the National Science Foundation, and others. In addition, universities, hospitals, clinics and nongovernment experts play a part in such decisions, not to mention the contribution made by literature emanating from the scientific community in general.

Increase in Appropriations

The Department and the Congress have certainly not been unaware of these various influences and the problems they create, and have been most helpful and considerate. This fact is demonstrated by the increase in our appropriations from slightly less than $7 million

in 1957 to a current appropriation of approximately $30 million. We are of course very appreciative of this understanding and confidence. Although I am aware that there may not be total agreement on this point, we believe that the FDA has met these challenges and has given the Congress and the consumer an honest dollar's protection for every dollar spent. We sincerely believe also that we have done this with as little controversy or unnecessary burden to industry as is possible.

While there is a pressing need for additional resources, the budgets must reflect the rate at which we can assimilate the increases. This year's budget (fiscal year 1964) will continue the progress that has been made since fiscal year 1957. As a matter of fact, it represents one of the more constructive budgets we have had. It adds 635 people to our authorized staff, bringing the total to 3,867 and it increases our appropriations from $29,106,000 to $35,805,000. In addition, it will permit us to make substantial strides in solving the space and facilities problem by authorizing the construction of an additional laboratory building at headquarters and the modernization of four of the seven district office-laboratory buildings yet remaining to be modernized under a program begun in 1958.

We have, of course, had some problems of logistics. Our staff has increased from 1031 in 1957 to 3500 for the current fiscal year. Obviously, space, organization and procedures which work wonderfully well with a small organization cannot always be expanded without some pain.

Neither will the space which comfortably housed 400 chemists easily accommodate a thousand. In the field of instrumentation and methodology, as you have undoubtedly discovered in your own laboratories, the relative modestly priced instruments are no longer adequate or precise enough to meet the needs of modern science. Instead, sophisticated instruments embodying the latest electronic and automatic concepts and costing accordingly, are not only convenient but necessary.

Changes and Recommendations by Committee

Last year the Secretary asked another Committee of distinguished citizens to again take a look at the FDA and to make recommendations as to its needs and policies. This report was submitted about a year ago and received some attention at last year's joint meeting held

in this auditorium. As Mr. Boisfeuillet Jones indicated at that meeting, the Department and the FDA welcomed the constructive criticism and in general agreed with the recommendations. One of the most important of these was for a change in organization which would increase the role of the scientist in administrative decisions and to produce a scientific atmosphere which would encourage the highest type of applied research which would promote enlightened law enforcement. Another recommendation was that we should encourage voluntary compliance and not rely, in such a great measure, as the Committee members felt was the case, on regulatory or punitive action. Last month, Secretary Celebrezze announced the broad outlines of such a reorganization and we are busy now putting meat on the skeleton. We have recognized in a greater measure the scientific side of our administrative decisions. We have created the position of Associate Commissioner which has not yet been filled, who will be an outstanding scientist situated at the right hand of the Commissioner and who will provide the scientific ingredient that the Committee recommended. Additionally, we have divided our present Bureau of Biological and Physical Sciences into two units: one dealing with the procedural scientific matters, such as the processing of petitions, and the establishment of tolerances; whereas the other bureau will be dedicated primarily to research. We have created a new Bureau of Education and Voluntary Compliance which will be dedicated to helping industry to understand what the law requires and to do whatever we can to prevent violations before they occur. This should further develop a climate for voluntary compliance through the maximum of understanding between industry and the Agency. A third recommendation of the Committee which we have adopted is the combining of what was formerly the Bureau of Field Administration and the Bureau of Enforcement into a new unit called the Bureau of Regulatory Compliance. We believe that this marriage will work toward a smooth flow of work processes and more efficient operation.

I have not given you all of the details of this reorganization but assure you that there will be no dramatic change in our method of operation. We are always glad to talk things over and although you may be talking with different people than before, their administrative and scientific resources and their desire to be helpful remain the same.

We are beset with one problem that is causing us real concern. Scientists, in order to be happily employed, need a challenge. This we can provide in abundance. They also need adequate salary and

here we are not as adequately provided. Despite recent government-wide legislation designed to raise federal salaries, FDA, along with other agencies in need of highly specialized skills, is still lagging behind universities and industry. This is particularly true with respect to medical officers where FDA can pay anywhere from a quarter to a third less than physicians can earn as teachers in our medical schools or in private practice. The salary rates that FDA can pay for pharmacologists, chemists and other scientists are likewise inferior to those in private industry and universities can provide. We have been able to make substantial improvement under the scientific super grade legislation enacted last year, but still lack the ability to pay some of our staff, salaries competitive to industry and private institutions.

Automatic Data Processing Equipment Employed

One of the tools we are employing with increasing frequency to improve internal operations is automatic data processing equipment. Automatic data processing systems have been developed to assist in scientific research projects, to improve program planning, to expedite retrieval of information developed during inspections and analyses in the field, and more recently to process information received in investigational drug proposals and new drug applications. There is now in progress a study of FDA by an outside contractor to assess the feasibility of establishing additional systems for the retrieval, utilization, dissemination, and exchange of scientific information and data.

There are now pending in Congress proposals for new legislation needed to improve FDA's ability to protect consumers. These include extension of factory inspection authority (which will be discussed later in some detail), premarketing clearance of therapeutic devices for safety and effectiveness, premarketing clearance of cosmetics for safety, and controls over the manufacture and distribution of habit-forming barbiturates and amphetamine drugs. Unless and until new legislation closes these gaps, FDA's ability to provide adequate consumer protection is seriously handicapped.

The job confronting FDA is not an easy one. The responsibilities are awesome. The food and drug industries of the nation share these formidable responsibilities with us. This presents many opportunities for industry and government to work together to achieve the highest possible degree of consumer protection. But this desirable result cannot be achieved without cooperation. An important element con-

tributing to cooperation is understanding. Those firms represented here today are to be commended for the interest shown by participating in this forum which is designed to promote a better understanding of our national food and drug laws. In the weeks and months ahead we hope every opportunity for interchange of views and ideas between government and industry will be utilized in the interest of achieving better understanding of the common problems we face.

[The End]

FDA ESTABLISHES INSTITUTE FOR CHEMISTS

Officials of the Food and Drug Administration and Georgetown University, Washington, D. C., have announced the establishment of an "FDA Institute for Advanced Analytical Chemistry."

The Institute will offer four 12-week courses each year of intensive study of advanced theory and applications of instrumental methods to analytical chemistry. The first course will begin January 6, 1964.

George P. Larrick, Commissioner of Food and Drugs, said "This Institute is being established so that FDA scientists can continue to keep abreast of the latest advances in analytical chemistry and apply the most up-to-date instrumentation to their work." He said the Institute "is a significant step in FDA's career development program."

Commissioner Larrick said an FDA committee consisting of Reo E. Duggan, Chief Chemist, Bureau of Field Administration, Dr. Henry F. Fischbach, Director, Division of Food, and Rupert F. Moure, Personnel Officer, Division of Personnel Management, developed the Institute's course in collaboration with Georgetown University's chemistry department. He added that the committee will work with the FDA Institute.

Dr. Louis C. W. Baker, Chairman, Department of Chemistry, Georgetown University, said the Institute will provide the most comprehensive course of full-time instruction in instrumental methods of advanced analytical chemistry now available. Instruction will be given by the faculty of the Georgetown University Chemistry Department. The professor in charge will be Dr. Charles F. Hammer.

Dr. Baker announced that enrollment in the course will be limited, with FDA chemists having enrollment priority. Graduate credit will be given to students who meet the requirements of the Georgetown University Graduate School.

The course will include lectures and laboratory work in chromatography, electrochemistry, radiochemistry, and the various types of spectroscopy, including ultra violet, visible, infrared, nuclear magnetic resonance, X-ray and mass spectroscopy.

Because of the research and analytical programs on all types of foods, drugs, cosmetics, and hazardous household commodities, the FDA is required to operate extremely versatile and comprehensive chemical, biological, and physical laboratories, FDA officials explained. Full and prompt use of continuing advances in science and technology are essential to provide maximum consumer protection.

The Need for Education in the Food and Drug Field

By PAUL S. WILLIS

Mr. Willis Is President of the Grocery Manufacturers of America, Inc.

IT IS NOW 25 years since our major law, the Federal Food, Drug and Cosmetic Act, governing the manufacture and sale of food, drugs and cosmetics, was enacted. Since that time it has been greatly strengthened in its protection of the health and pocketbook of the consumer by the enactment of amendments regulating the use of pesticides, food additives and color additives.

Because of the complexity of modern life, and particularly the complications resulting from the advances of scientific research in the food, drug and cosmetic fields, naturally our government and industry had to make numerous adjustments, some of them quite difficult, in order to meet the legislative changes. Certainly, all concerned have diligently devoted themselves to this task in such a way as to best protect the consumer and to serve the public interest.

During this 25-year period, our industry and the Food and Drug Administration have faced these problems in a spirit of mutual confidence and cooperation, with the realization that both are seeking the same goal. However, the Second Citizens Advisory Report on the FDA, filed with the Honorable Anthony J. Celebrezze, Secretary of Health, Education and Welfare on October 25, 1962, emphasized that FDA should develop still better approaches along preventive lines of enforcement.

It also stated the opinion of the Committee to be that FDA had not taken adequate measures to implement the recommendations of the First Citizens Advisory Committee regarding education, and urged a genuine program of government-industry cooperation as a fundamental means of coping with the growing problems of consumer protection.

Steps Taken in Recent FDA Reorganization

Thus, we welcome the steps taken by Secretary Celebrezze to implement the salient features of the Committee's recommendations in his recent reorganization of the FDA. This reorganization upgrades scientific functions of the agency, and emphasizes its educational functions by the creation of a new Bureau of Education and Voluntary Compliance. This will include a Division of Advisory Opinions, formerly in the Bureau of Enforcement to answer industry inquiries on compliance problems. This Bureau will also include an Industry Education Branch, and the Consumer Educational Branch and Consumer Inquiry Section from the present Division of Public Information, and the Consumer Consultant Program formerly in the Office of the Commissioner.

We believe the steps taken should result in improving the exchange of information between consumers and government and between industry and government. In saying this we do not overlook the fact that FDA is a regulatory agency, and that the police powers granted to it are the source of its real authority and influence which must be effectively used in the public interest.

On the other hand, we cannot expect the FDA to be the only source of education. 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 and cosmetics to the consumer. We, in the Grocery Manufacturers of America, have endeavored for many years to educate industry about consumer views in numerous ways, including our Consumer Service Committee which works closely with the FDA Consumer Consultant Program. Many in our industry have supported The Food Law Institute program of education. For several years the Institute has furnished courses of education in this law at the graduate level in a number of law schools in our leading universities. More recently it has provided Food Science Seminars which have included up-to-date instruction on the requirements of this law for technical, production, management, sales and marketing personnel. I commend the Institute to you as an organization which merits your membership support.

For a number of years it has been suggested at these joint conferences that some means to facilitate FDA-industry communications should be established. This resulted during the past year in the formation of a seven-member Food Industry Liaison Committee, of which I am a member. Our Committee's activities were described

by George P. Larrick, Commissioner of Food and Drugs, in his talk of November 12, 1963, before the 55th Annual Meeting of GMA, as follows:

(1) To improve voluntary compliance with the laws by industry through more knowledge of the requirements.

(2) To provide information about food industry problems to the FDA and thus promote better informed administration of the pure food law.

(3) To develop greater understanding of FDA laws and regulations by the general public.

We join with Commissioner Larrick in high hopes for this Committee's future activities.

Independent Responsibility of Industry

So far I have spoken mainly of shared responsibilities. I would like to emphasize that industry has an independent responsibility. Naturally, it does not always see eye to eye with government as to what is in the public interest. In such instances, industry must exercise its right to be heard, and should receive favorable hearing so long as it takes a constructive view of the matter. Industry should also be expected to test government regulations in the courts when such action is indicated to make certain that the powers granted by Congress have not been exceeded. It is in the public interest that we should do this and our long history of liberty through law confirms that this is so. It is not government officials alone who can always realize what is in the public interest.

The speakers who follow me will discuss these various matters at greater length. **[The End]**

UNPROCESSED LYSERGIC ACID DRUG SEIZED

Approximately 75 pounds of whole ergot—a drug from which LSD-25 and other lysergic acid derivatives may be manufactured—has been seized at Palos Verdes Peninsula, California. The seizure is the first such action based on failure to comply with the registration requirements of the Kefauver-Harris Drug Amendments of 1962.

Papers filed in the Los Angeles Federal District Court charged that the ergot was misbranded because the manufacturer had not registered with the FDA as a drug manufacturer. The Kefauver-Harris Drug Amendments require that all manufacturers of drugs, repackers and others register with FDA by the end of each year.

This drug is considered one of the most powerful chemical agents known.

The Food Industry and Free Enterprise

By R. L. GIBSON, JR.

Mr. Gibson Is President of Libby, McNeill & Libby.

IT IS MOST APPROPRIATE and significant that this conference coincides with the 25th anniversary of the enactment of the Federal Food, Drug and Cosmetic Act of 1938. This legislative milestone has become a symbol of intelligent and cooperative effort on the part of government and industry in the public interest. During the past quarter century, this law has been implemented by the Food and Drug Administration so as to create an atmosphere of good faith and mutual respect between the FDA and industry.

The continuing assurance of this cooperative climate—despite the tragic death of John F. Kennedy—is due to the dedication and determination of the vast numbers of civil and public service men and women who keep the wheels turning regardless of crisis. This is typically true of the FDA whose experience and efficiency inspires confidence in its continuing high performance despite temporary change or turmoil.

This type of freedom is synonymous with liberty, not license. It provides management with the liberty to seek the twin goals of economy and quality in its products. But it does not sanction a policy of license which permits irresponsible policies and practices.

Government-Industry Relations

The food industry confronts a situation common to all aspects of our economy. The four major parties concerned—the public management, labor and government—must take the statesmanlike view and realize that their interests are common interests and not conflicting ones. Each of these four groups share in progress and productivity. Naturally, there have been differences of opinion between the FDA and industry over the years—but honest disagreements which have been reconciled through mutual efforts.

If I were to capsule my conception of the proper role of government—including the FDA—it would be this. Government should *protect* but not *penalize*. These key words apply to all branches and functions of government. They also measure the intent and result of executive, legislative or judicial action. Protection involves preserving and defending the rights of every American citizen. But if this objective is sought through means which penalize unfairly any segment or group in our nation, then all groups are penalized.

When regulation becomes restriction, then it is not in the best interest of the public, industry nor the government. And if regulation becomes restriction, then it runs contrary to the theme of this conference, "Opportunities, Accomplishments, and Responsibilities in the Food and Drug Field."

Opportunities

Let me develop this theme more specifically by first considering the opportunities which challenge the food industry today.

Food for peace, in the broadest sense of the phrase, is probably our most potent weapon in the cold war. This was brought home dramatically to the world when Russia came to America seeking wheat because of her agricultural failures. Neutral nations impressed with Communist propaganda must now begin to realize that Communism cannot compete with free enterprise. Since we can produce *both* bread and bullets, then the world must know that capitalism is a dynamic system.

I don't for one minute discount the economic potential of the Soviet Union, however. If they concentrate their efforts on consumer goods rather than industrial and military might, they just might "bury us," as Mr. Khrushchev once threatened, if we relax our efforts.

Our opportunities are equally great in the Common Market and other parts of Europe. But here again we are faced with rough and tough competition. Productive capacity on the Continent has increased impressively in the years since World War II, and Europe's new factories, advanced technology and favorable government policies challenge us in every market. I do not fear this challenge, though, providing government, labor and industry team together to boost our exports. As indication of our partial success in this direction, the latest figures of the Department of Agriculture show that we increased our exports of canned fruits, vegetables and juices from 14,200,000 cases to 24,700,000 over a 10-year period.

But food supplies still fall far short of world needs. It is estimated that one-third of the world's population of approximately 3 billion people go to bed hungry every night. This means that we have both an opportunity and a mission—a chance for the food industry to make our diplomacy more powerful.

For example, let's consider Latin America. In my appraisal of world opportunities and obligations, I often feel that Africa and Asia haunt the headlines and are given most attention because they are currently in turmoil. But right in our own backyard—in Latin America—there is an opportunity and challenge we must meet. Latin America—the entire region south of our border—covers almost 8 million square miles, an area twice that of the United States. Its population, estimated at more than 200,000,000, is increasing at the rate of more than 5 million a year—the fastest growth rate of any major area in the world. This population explosion has outrun the agricultural increase and today less food is available per capita than 25 years ago! That means that an estimated one-half of the population—more than 100 million—lack the food they need. Here is both an opportunity and an obligation. True, one-fourth of our foreign trade is with Latin America and one-fourth of our direct foreign investments are in this area. But the unrest of the people, the instability of many governments, and the subversive activities of Cuba make Latin America our first concern.

But are we meeting this worldwide challenge? I don't think we are. And by "we," I mean government, management and labor. I am concerned about labor's insistence on higher wages without increased productivity. I am concerned about management's complacency and whether the new breed of professional executive has the dynamic drive of the old entrepreneur. I am concerned about increasing government controls that run counter to the principles of the free enterprise system.

Paths Toward Progress

Let me analyze for a moment how these three forces—government, labor and management—can contribute to our continuing progress.

From government we need tax relief for both the individual and industry and a reduction in high rates that penalize risk and investment of capital. This should be accompanied by every possible reduction in expenditure to bring them in better balance with our revenues.

We need continuation of sound regulations but freedom from unrealistic restrictions. Finally, we need the best efforts of government to eliminate discriminatory trade barriers especially in the Common Market.

From labor and labor unions we need assurance they will assume their proper responsibilities in our economic system. This means the elimination of featherbedding and poor workmanship. It means a good day's work for a good day's pay. This last is all-important because only through increased productivity can higher wages be justified. And only through increased productivity can we compete in export markets and reduce our dependence on tariff barriers to preserve our domestic markets.

Finally, management must make certain that men of integrity, ability and responsibility are at all levels of industry in this nation. From the foreman to the president of a company, these individuals must have vision, courage and confidence which will bolster the morale of our entire economic system and raise it to new heights of efficiency and effectiveness.

The teamwork of this task force can achieve the twin goals basic to our continued prosperity and progress. First, we must increase the productivity of our efforts and reduce the costs of operation. Secondly, we must continue to perfect new products and create new outlets for our goods so that industry of every type can expand its volume and improve its profits. Doing one without the other is insufficient. Thus, we must enlist the cooperative efforts of government, labor and management to achieve these goals.

Accomplishments

When we review our accomplishments, there is dramatic evidence in the food industry of major advances in technology, production and marketing—all to the benefit of the consumer.

For example, the United States Department of Agriculture recently completed a survey which updates results of a similar study in 1957. Six years ago a typical American family was boosting its budget substantially by buying convenience foods. Today, however, the most popular convenience foods cost less than their fresh counterparts. The Department of Agriculture's recent study showed that out of every $100 spent for food in grocery stores, $14.03 goes for convenience foods. The cost of an equivalent quantity of fresh foods is $15.10—a saving of $1.07 in favor of ready-to-serve items.

A good example is the economy represented by big money-savers such as frozen orange juice concentrate for which we have been spending 68 cents out of each $100 grocery bill. The equal in fresh oranges would have come to $1.39, according to the Department of Agriculture's study. There are many other examples of major cost-cutting convenience foods equally as startling. Furthermore, it should be noted that convenience foods permit a major saving in the housewife's working time. It is estimated that her duties in the kitchen now require only about one and one-half hours in comparison to five hours daily "in the good old days."

In addition, the record shows that in 1938, the year the Food and Drug Act was enacted, per capita consumption of canned foods was approximately 91 pounds compared to 138 pounds in 1962. This represents an increase of about 50 per cent in a little over 20 years, yet the price of canned foods has remained relatively stable.

Consumer Education

Our industry's concern for the consumer is not limited to quality and economy. Education is and has been another continuing objective.

Numerous programs are now in operation designed to enable the consumer to buy and use products more intelligently and effectively. Three laboratories operated by National Canners Association are devoted exclusively to research and technical problems and its Consumer Service Division tests and distributes canned food recipes and informative material. The Grocery Manufacturers of America also has a Consumer Service Committee with a similar function and both organizations work closely with the Consumer Programs Division of FDA.

Nutrition and the proper planning of meals is the vital function of such groups as the industry-supported Nutrition Foundation. Its past president, Charles Glen King, noted authority on this subject, has stated: "The producers of food are almost as interested in finding out more about the American family's food tastes, what its members of all ages require, would like to have or are dissatisfied with, as they are in research. . . . Food is closely identified with an individual's personality. Nutrition scientists know from study and experiments that good eating habits and sound nutrition help both child and parent to do his best and be at his best—on the job, in school, with friends or relaxing at home."

These efforts on the part of industry might well be supplemented by an expanded FDA effort in this direction as recommended by the Citizens' Advisory Committee Report. This group urged that FDA intensify and expand its educational programs.

These are sound and desirable goals, in my opinion. In the area of consumer protection, the emphasis should be on voluntary compliance since this approach is far more effective than relying solely on policing methods. This does not mean that there should be a relaxing of the present inspection, control and enforcement activities of FDA.

I am sure that industry leaders would agree with me that education and cooperation cannot completely replace investigation and prosecution in certain cases. On the other hand, the regulatory burden of FDA can be much more realistically managed if there is a maximum of consumer and industry understanding.

Responsibilities

This comment leads into the third phase of my remarks dealing with responsibility—since we have already touched on opportunities and accomplishments which comprise the other topics of this conference.

Responsibilities should be shared by industry and the FDA working as a team to carry out the purpose of the law by developing together a better understanding of its objectives and requirements. How can this best be done? Industry should observe the intent and letter of the law and serve the interest of the consumer by promoting voluntary compliance; government should use its inspection powers as an educational tool as well as for punitive action. This approach should insure a harmonious working relationship which is best for all concerned. A responsible industry must be strong, self-sufficient and unhampered—aware of its obligations to the consumer and strive to realize its potentials in the world markets.

Two factors contribute toward building industry which can be a credit to democracy—profits and pressures. Profits are the natural and legitimate goal of free enterprise. They provide the incentive for labor and management as well as making possible industry's tax contribution to the government. Pressures take diverse forms but all operate to prevent excessive emphasis on profits. Questionable practices in production, packaging or merchandising will soon estrange the consumer and cost any company the additional profits it sought through questionable shortcuts. The pressures of competition among

companies in the same industry provide safeguards which work against sharp practices.

Pressures derived rightly—but applied reasonably—in the form of government regulations is a third means of insuring protection and full value for the consumer.

The importance of enlightened self-interest is recognized by Senator Philip A. Hart of Michigan, author of the Packaging and Labeling Control Act now under consideration. Senator Hart has stated: "Government can either be helpful or oppressive and if I am going to be labeled, I hope the judgment would be that my label should be pro-public. Every action the government takes affects the whole nation. Our function is to serve as a watchdog for the free enterprise system."

This is a constructive attitude but the legislative proposal bearing his name runs counter to this philosophy. It concentrates on restriction rather than on protection.

Again, the proper measure of this bill, or any other legislation, is whether the emphasis is on restriction or regulation. It has been established that many provisions of the Hart Bill are already covered by existing laws and the additional expense of the bureaucratic paternalism would penalize the consumer as well as industry. Both would be penalized instead of protected as a result of requirements which involve costly changes and expenditures, vague demands and difficult enforcement procedures.

My position is supported by the testimony of Milan D. Smith, executive vice president of the National Canners Association, before the Senate subcommittee this year, when he stated: "It is our conviction that Senate Bill 387 is unnecessary, will not serve the best interests of the consumer, will tend to disrupt programs developed over decades of sincere industry efforts and may well greatly retard further improvement and development of canned foods."

This position is further supported by the American Bar Association which disapproved the measure in principle last August on grounds that it would delegate arbitrary administrative authority to issue regulations without practical guidelines. It is not my purpose, however, to attack in detail this single example of what I regard as the wrong approach to consumer protection. We should instead consider the broader and more fundamental relationships of government, industry and the consumer. I don't think it is unwarranted to assume

that the consumer today is intelligent, well-informed and capable of making a discriminating choice.

Any legislative act or administrative action is woefully wrong which attempts to dictate the consumer's choice, or presumes that the consumer is a primitive illiterate who should be told what to buy and how to spend his money. This is contrary to fundamentals of our social, economic and political system. America has grown great as a result of free enterprise functioning under democratic disciplines.

This national educational conference jointly sponsored by the FDA and Food Law Institute is dramatic testimony to the constructive and cooperative spirit which has teamed government and industry together in the public interest. This joint obligation to the consumer is a recognized responsibility.

At the same time, we must be alert to our larger opportunities represented by the world market which is the economic arena in the cold war between Communism and democracy. Here food for peace is a potent weapon. Here we can truly live up to the theme of this conference—take advantage of our opportunity, capitalize on our accomplishments, and meet our responsibilities.

In the 25 years since the enactment of the Federal Food, Drug and Cosmetics Act much has been accomplished. The next quarter century promises even more. If industry and the FDA face this future in a spirit of mutual confidence, then there is no limit to what we can do. With government, labor and management teaming together under the free enterprise system, *trade* can replace *aid* and *bread* can replace *bullets*. **[The End]**

FDA PROPOSES REPEAL OF CHLORDANE TOLERANCES

No residues of the pesticide chlordane would be permitted on food crops, under amended regulations proposed by the Food and Drug Administration. Tolerances for residues of 0.3 part per million are now in effect for 47 fruit and vegetable crops. These were established by FDA in 1955.

Pointing out that methods of determining the safety of pesticide residues have improved considerably since that time, FDA said that re-evaluation of chlordane toxicity data indicates that they are inadequate in the light of present information. An FDA proposal to repeal the existing tolerances for the chemical was published in the *Federal Register* of December 5, 1963.

Any person who has registered with the United States Department of Agriculture or filed under the Insecticide, Fungicide, and Rodenticide Act an application to register an economic poison containing chlordane may, within 30 days, request that FDA's proposal be referred to an advisory committee. The law provides that such a committee be nominated by the National Academy of Sciences.

Comments on Powers of FDA by Industry Spokesman

By DR. THEODORE G. KLUMP

Dr. Klump Is President of Winthrop Laboratories.

IN THE ENTIRE HISTORY of Food and Drug Legislation and Regulation one name stands out above all others. It is the name of Dr. Harvey W. Wiley, rightly referred to as the Father of Food and Drug Legislation. It was his dedication and crusading spirit that brought about the passage of the Pure Food and Drug Act of 1906.

History teaches that an inspired evangelist is not necessarily or indeed often an inspired administrator or a solid scientist. Dr. Wiley was apparently no exception. In 1908 he conducted a series of his own clinical tests from which he concluded that benzoate of soda and saccharin were injurious to the health of users and requested President Theodore Roosevelt to ban their use in foods and drugs. Of course, no one has ever accused Dr. Wiley of improper motives or of rigged research. His integrity and good faith are beyond dispute. In fact, that is what sharpens the point of the incident. Dr. Wiley stated that the President had decided to follow his advice on benzoate of soda and reversed it only on learning of Dr. Wiley's position on saccharin. President Roosevelt angrily characterized Dr. Wiley's position in these words: "Anybody who says saccharin is injurious to health is an idiot." Only because of the coincidence that President Roosevelt's own physician had previously prescribed saccharin for him was the American public spared the enormous loss, inconvenience and wrong that would have followed the banning of these safe and highly useful ingredients.

Appointment of Remson Board

This incident led the President to appoint a Board of outstanding scientists, the so-called Remson Board, to investigate the toxicity of benzoate of soda and saccharin. Following their report which, of course, gave a clean bill of health to these substances, President

Roosevelt became disenchanted with Dr. Wiley as a scientist and administrator. He designated a Board to run the Food and Drug Administration. Shortly thereafter, Dr. Wiley left and joined the staff of the magazine *Good Housekeeping*. Despite the question of Dr. Wiley's aptitude as an administrator, there was never any question of his dedication to the cause of pure foods and drugs and the protection of the consumer from injury, deception and fraud. No man, living or dead, had a greater and more enduring influence toward this end.

Dr. Wiley also left his imprint on the FDA in other respects. His successors as head of this agency, almost all of them his "boys," have been characterized by the same intense, unswerving devotion to the public welfare. The FDA has been singularly fortunate in having a lineage of administrative officials wholly and uncompromisingly dedicated to their tasks.

While this devotion to a mission is fortunately not unique in governmental service, it would be purposeless and uncritical to profess that all governmental employees are equally devoted. With this in mind, I have no hesitation in saying that it would be difficult, if not impossible, to find a more earnest, conscientious and effective group of workers than those who have been and are responsible for the affairs of this organization.

New Note Introduced into Operations of FDA

During its more than half century, the FDA has been permitted by the various administrators and secretaries of the departments of which it has been a unit to enjoy a high degree of automony. This in itself served to insulate it against political interference. Nor has there ever been a political appointee to a position of importance in the organization. However, former Health, Education and Welfare Secretary Flemming introduced a new note into its operations. More than any of his predecessors, he became the spokesman for the FDA, conducted press conferences and public meetings concerning its affairs and identified himself widely with the agency's decisions. This reached a peak of notoriety in the now famous "cranberry" incident. There is a serious question in the minds of many who have a high regard for the FDA and are sympathetic with the objectives for which it has so vigorously striven, whether his action in bringing this agency into the political spotlight was a beneficial step from a long-range point of view.

Reliance on Litigation

It is a strange and paradoxical fact, and perhaps yet understandable, that as an agency of government the FDA has had tough sledding until the last few years. In the first place, the Food and Drug Act of 1906 left much to be desired. Administrative officials saw danger and deception on all sides, which under the law they were powerless to stop. At the same time, the FDA saw itself as a police agency whose duty it was to deal with alleged violations, large and small, exactly as the law prescribed, either by criminal citation or seizure of the goods. While the FDA devoted some time and effort to bring about voluntary compliance, nevertheless infractions were many, and more often than not these were referred to the courts. Over a long span of years the FDA brought more cases to the federal courts than any other governmental agency, and its successes in such actions made a record of which the FDA has always been proud. As a result, administrative officials stepped on many toes and aroused the resentment of many who felt that they had received unduly harsh treatment. This resentment was, of course, conveyed to their representatives in the Congress, some of whom, no doubt, expressed their displeasure when the appropriations for the FDA came up for consideration.

More Efforts Toward Voluntary Compliance

With the added power and increased appropriations that flowed from the new Food Drug and Cosmetic Act of 1938, the FDA lost some of its inferiority complex. The impulse to over-react was diminished. With the poise that comes with strength and power it could now afford to direct more of its efforts toward voluntary compliance and education, and proportionately less reliance on litigation as an instrument of obedience. Its officials followed President Theodore Roosevelt, their first Chief Executive's injunction to speak softly and carry a big stick. In this more relaxed atmosphere the regulated and the regulators were at least on speaking terms, and many mistakes on both sides were nipped in the bud. Industry had an opportunity to comment informally on proposed regulations, new policies, and generally applicable administrative decisions. The regulated industries felt that the relationship was beginning to approach what it should be in a free society and in accord with the best traditions of our Republic.

Recommendation of Kendall Committee

However, in 1960 a three-man task force under the chairmanship of Charles H. Kendall, a former FBI man, appointed by Flemming to study the operations of the FDA, recommended in effect that this policy be modified and that the FDA deal at arm's length, and to all intent and purpose in court, with those subject to its authority. The Kendall Committee report stated, "Because of the limitations and dangers inherent in it, we are of the opinion that industry self-regulation cannot be expected to fulfill the purposes of the food and drug law." It is significant that the Medical Services Task Force of the Second Hoover Commission on Reorganization of the executive branch of the government, which also studied the operations of the FDA, made no such recommendation and indeed complimented the Administration on its pattern of operation. In my opinion, this recommendation of the Kendall Committee was a retrogressive departure from the finest ideals of law enforcement in a democracy.

Not long after this blow fell, Senator Kefauver and the chairmen of other Congressional committees directed their attention to the FDA. As might be suspected, they did not come to praise. In addition, two Citizens' Advisory Committees had studied the operations of the FDA and recommended changes in its pattern of operation.

In the face of all this critical attention, with more promised to come, and some of the unfair changes that had been made, it would be astonishing if the morale of the FDA had not suffered. Action in some directions was slowed down, and in others hasty steps were taken which might have been otherwise if the deliberate and orderly process of administrative consideration and consultation had been permitted to function. Furthermore, the agency lacked skilled and seasoned medical and technical personnel to help steer it through the troubled waters.

Trend of Regulation of Drugs

It is clearly evident that evolution of the regulation of drugs in the United States has steadily moved *away* from a system of *objective* standards fixed by law, interpreted and enforced principally by the courts. It has moved towards a regime of subjective administrative control over the investigation, manufacture, distribution and use of drugs. The policy of the FDA has been to develop detailed operating rules in these areas and then to make them binding upon the drug industry through regulations.

This trend was described in 1954 by Charles Wesley Dunn, the illustrious founder of this organization, as follows:

> The fourth trend is a growing FDA disposition to transform the 1938 ACT into a government permission control one, to a basic extent. This trend should be approached from the standpoint that the Act has been designed, since its 1906 inception, to express the legislative philosophy of free institutions in their application to private industry. . . . An exception to this philosophy, for the substitution of a government permission control over private industry, is only justified to the extent it is unavoidably essential to assure the public safety (Dunn, "Our Food and Drug Law with Some Observations on Its Major Statute," 9 FOOD DRUG COSMETIC LAW JOURNAL 383, 394 (1954)).

Since those remarks were made, the trend toward "government permission control" has proceeded with alarming speed. In fact, one is concerned whether the transformation has, in fact, been completed by the enactment of the Drug Amendments of 1962 and especially by the recent issuance by the FDA of the Regulations thereunder.

The FDA clearly supported this trend and continues to do so. For instance, in a speech delivered on January 25, 1961 before a committee of the New York State Bar Association, Mr. Harvey (Deputy Commissioner of FDA) frankly concluded that "a profound and continuing change" was occurring in the administration of the federal food and drug laws. The nature of this change, according to Mr. Harvey, was to substitute the FDA for the federal courts as the principal interpreter of these laws. This was made possible, he states, by "the development of administrative techniques," primarily the establishment by regulation of "the exact conditions that will constitute law compliance." Mr. Harvey felt that as a result of this change the individual "who wishes to abide by the law" need no longer wonder how the courts will apply the law to his product. He need only "abide" by the rules for compliance issued by FDA. This trend is interesting in the light of the following episode: When the 1938 law was being considered by the Congress, one of the all time most important figures in the drug industry sent his legal representative to Washington with the following instructions: "Above everything else, I am interested in one thing. Keep the door to the courthouse open."

That this evolution placed "very heavy scientific and legal burdens" upon FDA was readily conceded by Mr. Harvey. He stated that it requires scientific personnel "with an unusual degree of competence," and field chemists "who can analyze for a tremendous variety of chemical substances," and top management of FDA must spend "a large proportion of their time on the rule-making process." This will necessitate "a greatly increased staff in the field" to effec-

tively administer the new rules. (Harvey, "Evolution in the Food, Drug and Cosmetic Law Area," 16 FOOD DRUG COSMETIC LAW JOURNAL, 90 (1961).)

The inherent corollary to the above-mentioned trend from objective law to subjective agency discretion is the development of awesome powers by FDA not subject to effective judicial review, over matters falling within the area generally known as medical opinion. In other words, the effect of the exercise of nearly unlimited discretion in regulating the drug industry is to substitute in many respects the judgment of FDA for that of the physician, including the clinical investigator.

There is little doubt that our drug laws as opposed to the regulations thereunder do not establish FDA as the judge of medical opinion. Both the original Food and Drug Act of 1906 and the Federal Food, Drug and Cosmetic Act of 1938 intended to regulate only matters of objective fact.

As one court summed it up in 1944: "Plainly, therefore, the subject of regulation in the 1938 Act, as in its predecessors, is matter of fact, not matter of opinion." *United States v. 7 Jugs, etc. of Dr. Salsbury's Rakos,* FOOD DRUG COSMETIC LAW REPORTS, ¶ 70,125.087, 53 F. Supp. 746, 758 (DC Minn. 1944).

1951 Durham-Humphrey Act

An important recent instance where the original principles of the law were reaffirmed by Congress and in the face of strong FDA endorsement of radical change was the 1951 Durham-Humphrey Act. This Act revised the prescription drug law. One provision of the bill, as originally proposed and supported by FDA, empowered FDA to restrict to prescription sale those articles which it found to be unsafe or *ineffective* for use without the supervision of a physician. Substantial controversy developed over the propriety of this provision concerning efficacy and after considerable debate, it was deleted from the bill on the floor of the House of Representatives.

The fundamental objection to the controversial FDA-approved provision in the original Durham-Humphrey Bill was that it would permit an administrative classification of drugs unduly interfering with the practice of medicine. Thus, the American Medical Association went on record, in testimony given before the Senate Subcommittee on Health on September 13, 1951, in opposition to the provision authorizing administrative control over efficacy decisions:

A more basic objection to the provision in question is that it vests in the Federal Security Agency control of the drug industry and delegates to that agency the power to determine the therapeutic value of drugs—a decision which is a traditional and time-tested function of the medical profession. In this respect federally placed control of the drug industry, especially as to the effectiveness of drugs, will result in unnecessary and undesirable control of the practice of medicine. (*Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare,* United States Senate, 82nd Cong., 1st Sess., on S. 1186 and H. R. 3298 (1951), p. 213.)

Notwithstanding this Congressional action, the FDA thereafter achieved by means of administrative procedures much of the control over determinations of the efficacy of drugs, including relative efficacy in some cases, which it had unsuccessfully sought to obtain in Congress.

Again in the Drug Amendments of 1962 the FDA asked Congress to give it clear and unequivocal control over decisions dealing with the efficacy and safety of drugs. Once again, however, Congress refused the FDA this blanket control. It denied FDA's request for authority to withdraw a drug from the market if FDA entertained a *substantial doubt* as to its safety. Again Congress did not agree with FDA's position in which it sought full power over efficacy. The Congress only gave FDA authority to require a manufacturer to produce *substantial evidence* of effectiveness before his product may be marketed. The legislative history makes it clear that Congress recognized that FDA sought to become the arbiter of medical opinion in the matter of efficacy. It is also clear that the authority that Congress did bestow in this area had to do with the quality of evidence that a manufacturer had to submit and withholds from the FDA the power to sit in judgment on the over-all question of a drug's efficacy or of a drug's relative efficacy.

Once more, therefore, we find Congress refusing to abridge the basic philosophy of our drug law by recognizing again that in the long run the physicians of this country must be the judges of a drug's efficacy and of its safety. Congress, however, has not stopped the trend and, judging by what has happened since the Drug Amendments of 1962 were enacted, we have every reason to expect that FDA will initiate further efforts to expand its jurisdiction in opinion areas through the promulgation of regulations and various other administrative techniques including use of the vast punitive sanctions that are at its disposal.

It may be asked, why has this trend been resisted? What it is that has raised such fears and concerns down through the years.

Effect on "Freedom" and "Progress"

What a system of subjective administrative control over matters of medical opinion means to "freedom" has been well stated by James F. Hoge who has studied this problem and all of its facets throughout his professional life:

> The national drug law is, of course grounded in the constitutional grant of power to regulate interstate commerce and, as such is fitted into the pattern of our federal government. To propose administrative controls on the possibility (more exceptional than usual in actual practice) of conflicting decisions among the district courts is to challenge the soundness of the federal system. To utilize delays incident to litigation as grounds for claiming the power of decision is to challenge the constitutional arrangement for the interpretation and enforcement of our statute law. To exalt impatience with the vagaries of the jury system is to betray impatience with one of freedom's fundamental concepts. To insist that there must be "somebody" to decide is to advocate a continuing need for decision and for the subjection of others thereto—a proposition rather strange in a society where initiative, responsibility and freedom have been the beacon lights. They are the lights which must not go out anywhere along the line of American enterprise. (Hoge, "Major Drug Law Problem," 6 FOOD DRUG COSMETIC LAW JOURNAL 933, 935 (1951).)

What a system of subjective administrative control over matters of medical opinion means to "progress" is this. In the entire realm of medical science nothing is more difficult and more subject to honest differences of qualified opinion than the determination of the therapeutic effectiveness or safety of drugs in human beings.

Despite advances in scientific techniques, therapeutic representations and claims, just as therapeutic safety, remain essentially matters of opinion. Different schools of thought with respect to the proper treatment of various diseases are prevalent and sometimes contradictory. Not infrequently, it takes years and sometimes decades of widespread clinical experience to evaluate the relative merit of a drug in given conditions. From such long experience, a medical consensus generally emerges but even then some qualified physicians refuse to go along with their colleagues.

History teaches that authoritarian bodies have often been guardians of orthodoxy rather than champions of progress. Medical experts rejected Jenner's smallpox vaccine, Pasteur's anthrax vaccine, Lister's theory of antisepsis and Semmelweis' discovery of the cause of childbed fever. Cod liver oil was rejected as worthless by the Council on Pharmacy and Chemistry of the American Medical Association. When Prontosil, the first sulfa drug was introduced in the United States, it was greeted as another quack remedy by an outstanding American authority on infectious diseases. In the early 1930s, the same author-

ity dismissed early English reports on penicillin as incredible and refused to employ for clinical testing a culture of penicillium that had been brought to him by one of his associates. He poured it down the sink.

By Whose Advice Is FDA to Be Guided?

At the present time, there are sharply opposed views among experts concerning the proper treatment of many common diseases. Rheumatoid arthritis is such a condition. There are highly qualified physicians who favor the use of corticosteroid drugs. There are others who feel that the employment of the corticosteroids does more harm than good and that the only meritorious drug is aspirin. Still others are proponents of respectively Butazolidin, gold salts and antimalarial drugs such as quinacrine, chloroquine and hydroxychloroquine. The reaction of experts to any new drug offered for the treatment of rheumatoid arthritis will inevitably be conditioned by the school of thought to which they happen to adhere. By whose advise is FDA to be guided in the evaluation of a new drug for this condition?

Epilepsy is an affliction for which a variety of drugs is available. For reasons not now understood, any one of these drugs may be effective in some cases of epilepsy and worthless in others. If a new drug were found to fail in 80 per cent of the cases in which it was tested and successful in the remainder, would it be released by FDA as "safe" and "effective" or would the clinical testing required be so extensive and costly that no manufacturer could afford to carry through such a program for the possibility of gaining only 20 per cent of a limited and already highly competitive market. If this were to happen, it might deprive a number of unfortunate epileptics of a drug uniquely effective in their particular cases.

Mucous colitis is a disease, the cause of which is still unknown. For almost a century it was considered to be due to intestinal infection from an organism as yet unidentified. In 1924, Bargen of the Mayo Clinic reported the isolation of a bacterium from cases of mucous colitis. This discovery was hailed as the revelation of the culprit responsible for the disease. It gave impetus to the use of antiseptic agents and later sulfa drugs and antibiotics in the treatment of the condition. Unfortunately, no drug was found to be uniformly successful and as a result other theories were advanced to explain the nature of the disease and to provide a rational basis for its treatment. Reputable surgeons, concluding that no drugs are effective, still remove large segments of the bowel. More recently, psychiatrists became

convinced that the condition was due to emotional disturbances and represented nothing more than an extension of the well-known diarrhea of fear and fright. At the present time these and other divergent schools of thought adhere to their theories. With all the various forms of treatment, some cases improve and others go on to death. Here again the attitude of medical officers of FDA, if given the authority to decide for all doctors the safety and effectiveness of new therapies, will be conditioned by the theories which they happen to favor.

Conclusion

I trust there is no need to go on with this litany. This audience surely knows that real progress comes only through controversy freely pursued, risk, experiment, and above all, the imagination of courageous pioneers who are willing to leave the well-trodden path of the past and strike out into the unexplored unknown. All this is made more difficult through excessively tight governmental regulation. Surely there is a middle ground in our democracy where the government can exercise its rightful function of supervision at the same time serving as a serious deterrent to progress.

As an alumnus of the FDA, I have a friendly feeling toward that organization and respect the dedication and good will of its leadership. They happen to think that they need vast and arbitrary powers, and to exercise these powers to do a good and effective job. I happen to believe, and fervently, that with the use of such powers our country will lose more than it gains. I must oppose the unlimited power they are seeking over medical matters and matters of opinion. I cannot forget that the first chief of the FDA started out wrong on the toxicity of saccharin and benzoate of soda. His successors from top to bottom, being mere mortals, will inevitably be wrong many times again.

The conquest of disease, the relief of suffering, and the prolongation of life are objectives so transcendent in importance that they justify every safeguard to avoid mistakes that may be more serious in their consequences than those made by Dr. Wiley. In the last analysis the medical profession should be permitted to be the arbiter of what drugs it wants and needs and every opportunity should be provided for appeal to and review by the medical profession of Agency opinions in this highly complex field.

The late President Kennedy said in his Inaugural Address, "Together let us explore the stars, conquer the deserts, eradicate disease, tap the ocean depths and encourage the arts and commerce."

[The End]

Factory Inspection

By EDWARD BROWN WILLIAMS

The Author Is a Partner in the Law Firm of Harter, Calhoun & Williams, Washington, D. C. and a Member of the Editorial Advisory Board of This Magazine.

I HAVE BEEN ASKED to discuss "factory inspection"—a kind of warmed-over topic, but it remains an important one. I am going to make just about one point. That it will take longer than it should in the making is, I suppose, one of the hazards which you assumed when you came here.

The term "factory inspection" is in the nature of an encapsulated description of what the Food, Drug and Cosmetic Act authorizes FDA representatives to do when they make official visits to food, drug and cosmetic establishments. It means, in the case of foods, nonprescription drugs and cosmetics, inspection of "pertinent equipment, finished and unfinished materials, containers, and labeling," whether in a "factory," a "warehouse," an "establishment," or "vehicle" where there are articles subject to the statute.

Prescription Drugs "Factory Inspection"

In the case of prescription drugs "factory inspection" means a great deal more than that, and there are plans to make it mean a great deal more than that as applied to foods, nonprescription drugs, devices, and cosmetics. The present broadly expanded inspection authority for prescription drug establishments was written into the statute by the Drug Amendments of 1962. Indications are, however, that the scope of the new authority is going to be disputed between FDA and industry just as was the old, more limited, inspection authorization which is still applicable to foods, nonprescription drugs and cosmetics; that FDA is going to demand more inspection rights in prescription drug establishments than industry believes the 1962 statute has granted. Such a circumstance, of course, does nothing to diminish the misgivings of industry about the prospect of broadening the inspection provisions applicable to establishments other than those affected by the Drug Amendments of 1962.

Harris Bill

A bill[1] is pending in the House of Representatives (the Harris bill) which would make applicable to establishments manufacturing or holding nonprescription drugs, devices and cosmetics, the expanded inspection authority of the Drug Amendments of 1962. The bill would grant the same authority to inspect food establishments, except with respect to certain research data.

The inspection would extend to "all things" in the plant, including records, files, papers, processes, controls and facilities "bearing on" any violation of the Act, with certain specified exceptions. As a practical matter, if an inspector thinks a record or file or formula bears on a violation of the Act he will demand the right to inspect it. The very fact that the business of a plant is making or holding articles subject to the Act would, I suspect, be regarded as a sufficient basis for inspection of any record relating to such business, unless the statute specifically excepts it from inspection.

The following things in a food plant, for example, would be subject to inspection: shipment data, data as to qualifications of technical and professional personnel performing functions subject to the Act, formulas and recipe files, quality control records, laboratory testing records (as distinguished from research files), complaint files, and processing records. Even personal records of plant officials are not excluded, since they are among the "things therein," that is, in the plant, and may bear on a violation of the Act. Nor does anything appear in the pertinent language which would warn the inspector against examining confidential communications between the company or its officials and their legal representatives or other consultants. These may "bear upon" a violation of the Act. Consulting laboratories would be made subject to the same inspection as the food establishment itself.

These new provisions now applicable to prescription drugs and proposed for other articles subject to the Act have been attacked by competent lawyers as unconstitutional under the Fourth and Fifth Amendments. The fact that these provisions have been enacted for prescription drugs does not, of course, render moot the question of constitutionality. Their validity has not been tested.

I do not propose to deliver a technical lecture on the legal considerations involved. Permit me, however, to point to certain aspects

[1] H. R. 6788, introduced by Mr. Harris, Chairman of the Interstate and Foreign Commerce Committee.

of the question which have not received the emphasis which I believe they deserve.

Dotterweich Case

The Federal Food, Drug and Cosmetic Act is a stark, liability-without-fault, criminal statute. As Justice Frankfurter said in the *Dotterweich* case:[2]

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—*awareness of some wrongdoing.* (Italics supplied.)
>
> Hardship there doubtless may be under a statute that thus penalizes the transaction though consciousness of wrongdoing be totally wanting.

Not only is the corporation subjected to such strict liability but individuals who have a responsible part in the conduct of the business may be punished criminally for statutory violations of which they are unaware and regardless of fault or negligence.

Dotterweich was president and general manager of the Buffalo Pharmacal Company. He was prosecuted, along with the company, for shipment of misbranded and adulterated drugs. Guilt was imputed to Dotterweich, as the dissenting Justice said, "solely on the basis of his authority and responsibility as president and general manager of the corporation" without proof or claim that he ever knew of the offending shipment, much less that he actively participated in it.[3]

It is one thing to back up the enforcement of such a strict liability statute by inspection limited to a plant and pertinent equipment, finished and unfinished materials, containers, and labeling. It is quite another to back it up by delving into confidential files, perhaps even files personal to an individual, which may relate to trade secrets, to conditions or activities which are not violative of the statute, misleading or irrational complaints by customers, or projects which have been abandoned; or which may consist of personnel data embarrassing to individuals but without any real bearing on enforcement of the statute.

This is the kind of thing now facing officers of firms of prescription drug manufacturers and which is planned for responsible individuals in the rest of the industry.

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[2] *United States v. Dotterweich,* FOOD DRUG COSMETIC LAW REPORTS, ¶ 2151.25, 2211.261, 320 U. S. 277, 280, 281 (1943).

[3] Cited at footnote 2, at p. 286.

Privilege Against Self-Incrimination May Not Be Invoked

That is not all. The privilege against self-incrimination may not be invoked by the custodian of corporate records to avoid the production of such records under court order. The corporation does not enjoy the privilege and the custodian, acting as its agent, is bound by its obligations. But remember that in such a situation—where production is ordered by the court—the scope of the order to produce and the relevancy and materiality of the incriminating files are passed upon in a judicial proceeding with all of its safeguards of the individual.

This is remote indeed from the case of the free-ranging inspector who may examine and copy both corporate and personal files under the exceedingly broad authority of the provision in question. Here there is no judicial safeguard to assure relevancy and materiality or even that the examination of the files will be conducted within statutory restrictions. Yet the data so obtained may be freely used as the basis for building the edifice of criminal prosecution, not only of the corporation, but of individuals without awareness that a violation has occurred.

There is no need to recite here the ringing declarations of the doctrine of fairness, right to privacy, or privilege against self-incrimination, which are found in our jurisprudence. The tradition which such pronouncements reflect is *not* reflected in the kind of largely unrestrained rummaging around in confidential papers and records which would be permitted by the proposed law.

Individual Owners and Operators Not Immune

Remember also that the individually owned and operated drug store and grocery store are not immune from this scrutiny of their affairs, and that they do not even have the legal advice available to the substantial corporation upon which to base any opposition to unlawful demands. It is not an answer to say that the Secretary is authorized to exempt such classes of persons upon a finding that inspection of their establishments is not necessary for the protection of the public health, as is provided in the Harris bill. Such a choice of largely uninhibited inspection, or of less than that, should not be left to the discretion of the Secretary.

Let me underscore the situation. A corporate officer, because he is in a position of responsibility, may be convicted of a criminal violation of the Act of which he was unaware, on the basis of the content of records of which he had no personal knowledge, which were ob-

tained by a routine inspection made with no basis for a belief that a violation had occurred.

In the case of food, drug and cosmetics establishments generally, we are not talking about the situation where the statute specifically requires the regulated firm or individual to keep records in aid of enforcement of the regulation, or where the securing of a license is a prerequisite to the operation of the business. In such cases, where the state legislature or the Congress deems the selected business to be one sufficiently affecting the public interest to require the keeping of records specified by statute or regulation, or to require licensing supervision, or both, the courts have recognized the paramount right of the government to inspect the required records.

Such a requirement exists under present law, in the case of statutorily designated drugs—new drugs and antibiotic drugs—which are subject in effect to licensing control for reasons deemed sufficient by the Congress, and would apply to new cosmetics and new devices under the Harris bill. The bill proposes, however, no such control for other drugs or devices, or for foods. Licensing control over the huge food industry would be a gigantic task indeed.

As a matter of basic traditional principle the extreme scope of the proposed inspection authority for foods, drugs and cosmetics generally, coupled with the statutory concept of liability without fault or awareness of violation by individual citizens, would constitute a sharp departure from the fundamental rules of fairness and the privilege against self-incrimination which have always been deeply imbedded in our jurisprudence. This is a thing of principle and any departures from that principle should be carefully scrutinized and circumscribed.

As a matter of precedent, therefore, the statutes which have been cited to the Congress in support of the validity of largely unrestrained inspection authority, which require specified record-keeping or licensing, are of little if any applicability. Likewise, other enactments which have been cited in support of the expanded authority, which grant statutory immunity from prosecution to persons required to testify or produce records, are equally inapplicable.

Subpoenas to Attend and Testify

A provision of the Harris bill [4] would authorize the Secretary to issue subpoenas "requiring the attendance and testimony of witnesses,

[4] Sec. 103, H. R. 6788.

or the production of any books, records, correspondence, documents, or other evidence" that the Secretary deems relevant in any hearing under the Act.[5] District courts of the United States would be authorized to enforce compliance with such subpoenas. No person could be excused from obeying the subpoena on the ground that the testimony or evidence required of him may tend to incriminate him or subject him to a penalty or forfeiture, but a *natural person* claiming the privilege against self-incrimination may not be prosecuted on account of any transaction or other matter with respect to which he is compelled to testify.

Under such a provision the person to whom the subpoena is directed is entitled to have the validity and scope of the subpoena tested in a district court of the United States in accordance with applicable constitutional and other legal principles and, as an individual, he may, by invoking the privilege against self-incrimination, protect himself against prosecution.

The proposed provision presupposes a proceeding with a specific subject matter to which the information subpoenaed is considered relevant. This plainly is an entirely different matter from the kind of inspection, starting from scratch with the aim of looking for possible, unsuspected, violations of law, which would be permissible under the proposed inspection authority. If a power of subpoena were granted to the FDA of a scope comparable to that of the proposed power of inspection, it would be subjected to limitations by the courts which are not practicable in the case of factory inspection, where judicial participation ordinarily occurs only when a legal action is brought for violation of the statute, which may, of course, be a criminal prosecution.

American Tobacco Company Case

The scope of the statutory authority of the Federal Trade Commission to have access to and the right to copy any documentary evidence of any corporation being investigated or proceeded against, and to require by subpoena the attendance and testimony of witnesses and the production of such evidence, was considered by the Supreme Court in the *American Tobacco Company* case in 1924.[6] The court's language is peculiarly apt in considering FDA inspection proposals. Justice Holmes stated:

[5] What hearings are meant is not specified.

[6] *Federal Trade Commission v. American Tobacco Company*, TRADE REGULATION REPORTS, ¶ 9571.95, 264 U. S. 298 (1924).

> It is contrary to the first principles of justice to allow a search through all the respondent's records, relevant or irrelevant, in the hope that something will turn up . . . Some evidence of the materiality of the papers demanded must be produced.[7]

Since that proceeding was a petition in the district court for enforcement of the subpoena, respondent had an opportunity to contest the validity of the subpoena, and did so successfully, before being subjected to any legal action by the Commission based upon the evidence illegally sought by it. Contrast such a proceeding with the situation which obtains under the Food, Drug and Cosmetic Act for the prescription drug industry and which is proposed for the other food, drug and cosmetic industries subject to the Act.

During the New Deal days a labor union staged a musical show which featured a number called, "Let's Sing a Song of Social Significance." "Social Significance" tells government when and how far it should interfere with and regulate the lives of the people and their business and social pursuits. "Social Significance" was very big in the New Deal days, as it is today.

Conclusion

Long ago, when the Roman Emperor called Caligula, which means Little Boots, went out looking for the Germans and couldn't find them, he dressed up half his army as Germans and pursued them with the other half. I do not suggest that the government regulators will grow to constitute half the people and go out to impose their controls on the other half, or that the regulators are out chasing chimeras. Sometimes I fear, however, that the growth of government inroads into our lives, fired as it is by more and more "Social Significance," is turning in upon itself.

Regulation is becoming so pervasive that it is beginning to engulf not only those who without it might harm society, but those who are supposed to be benefitted by it. Some regulation is clearly and concededly necessary, but when it takes the form of inspection, search, and ensuing criminal prosecution of individuals without awareness of guilt, on the vast scale proposed for the food, drug and cosmetic industries, I think, as I know many of you do, that is going out of bounds. **[The End]**

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[7] See also *Oklahoma Publishing Company v. Walling*, 327 U. S. 186, 10 LC ¶ 51,222 (1946).

Scientific Bases for Food Laws

By PAUL R. CANNON, M. D.

Dr. Cannon Is Professor Emeritus of Pathology, University of Chicago, Chief Editor, *Archives of Pathology*, American Medical Association, and a Member of the Food Protection Committee.

PROFESSOR CLARENCE CARSON, in discussing the subject of voluntarism in a recent issue of *The Freeman* (October, 1963), has said: "Man is a flawed being. He is given to enthusiasms about what is good for other people. Under the sway of these he wishes to prescribe and enforce by law the particular sorts of undertakings that accord with his vision. . . . He fears that if whatever he wants done is not made compulsory, it will not be done. . . . If the matter is left to choice, some will neglect that which is desirable." This quotation epitomizes the protest of a modern libertarian against the coercive trends of modern liberalism.

Gratuitous Advice Harmful

To the above protest I wish to add another. It, too, emphasizes a type of flaw common to us all, namely, the compulsion to give gratuitous advice. This flaw manifests itself at all levels, from bleachers to preachers, and at all times, from the cradle to the grave. It does not refer to professional advice given in line of duty; that kind, of course, actually is not given; it is paid for. The kind of advice I have in mind is that customarily represented by letters to the editor, letters to congressmen, to the White House and to FDA, letters from health and food enthusiasts, religious zealots, etc. I suggest that most of this advice would be harmless were it not for the fact that much of it is taken to heart. Therein lies the harm.

Two Questions to Consider

Today I wish to consider two questions which have been of especial interest to us of the Food Protection Committee. One deals with the general question of communication between scientists and the general public on matters of scientific significance, and the other,

with the more specific relationships of food additives to disease, including cancer.

In considering such questions we have to realize that we are concerned with the desires of an uninformed public for vigorous action by its elected representatives and governmental agencies, and that among the uninformed there are many exaggerated fears concerning the possible health hazards of our changing environment. Although not much can be said about such questions in 20 minutes, we can at least interrogate ourselves with regard to certain phases of the underlying problems.

In pondering these questions one wonders to what degree many of today's fears and apprehensions might be lessened if better methods could be devised for informing the public about basic principles of disease. For example, why should so many be so easily persuaded by books, magazines and newspapers that we all are being insidiously poisoned by the food we eat and the air we breathe? Why do so many seem to prefer to believe that nothing is being done about the environmental hazards of modern living and that this presumed neglect is due mainly to the heartless selfishness of commercial interests and the indifference or laxity of governmental agencies? Why do so many persons seem to believe that toxicity and hazard are synonymous conditions? Why do so many assume that a poison is a poison, regardless of amounts and conditions of use?

Because of these fixed beliefs pressures are continually being brought to bear on congressmen and legislators in general to enact additional laws, rules and regulations to protect the public against the "selfish interests." Here again is re-emphasized Professor Carson's thesis that man is a flawed being who is too often concerned with his enthusiasms about what is good for other people, and, with the self-assurance of the uninformed, gives advice in areas beyond his spheres of experience and competence.

Facts or Speculations—No Difference

Another regrettable aspect is that these givers of advice too often fail to differentiate between facts and speculations. Such a tendency would be of little moment if the associated confusions did not also carry over into legislative actions based on inadequate foundations. In this connection one wonders why the public should be subjected to the irresponsible, fear-generating suggestions that a variety of diseases may be due to the presence of poisons in our foods. Are these

suggestions the manifestations of a general neuroticism, are they expressions of a kind of paranoid trend, or do they merely pay well? In any case our methods for counteracting them seem to be generally inadequate.

Although there has been a tendency since the advent of DDT to attribute the cause of almost any obscure malady to the use of pesticidal chemicals, lately it has become popular to postulate specific relationships between the use of pesticides and the rising incidence of leukemia and infectious hepatitis. The technique is the old and familiar one of the *post hoc, ergo propter hoc* type of reasoning. No one has suggested, however, a correlation between the incidence of these two diseases and increasing exposures to household detergents, television lights or gasoline stations. But because pesticides kill pests, apparently it is easy to assume that they must, therefore, be hazardous to human beings. Moreover, when toxicologists and other scientists point out the fallacies of such types of reasoning they are often accused of complacency, of venality, or of being chattels of the chemical industries. It might be added parenthetically that until recently, when the antipoliomyelitis vaccines gave the answer, pesticides were also accused of causing an increased incidence of this disease.

Rising Incidence of Leukemia and Infectious Hepatitis

With reference to leukemia it is indeed true that the reported incidence has risen in the past few decades. However, this incidence doubled between the years 1920 and 1940, a period before today's commonly-used pesticides had come into general use. On the other hand these two decades witnessed the unusually active increase in hospital facilities throughout the United States, including hematological laboratories, more frequent blood examinations, and an accelerated development of laboratory medicine through the rapid growth of clinical pathology. In consequence patients in increasing numbers had the advantages of more and better hospital facilities, including improved diagnostic opportunities and methods for the diagnosis of leukemia, as, for example, through the more general use of x-rays for its diagnosis and treatment. In any case there is no valid reason to assume, and there is less evidence to conclude, that pesticidal chemicals have had any important relationship to the genesis of leukemia in man.

Another example of the fallacy of the *post hoc* type of reasoning is seen in the suggestion that the widespread occurrence of infectious hepatitis may be related to the use of pesticides. Here it is assumed

that, inasmuch as many of the pesticides, such as DDT, are hepatotoxic agents, they might be causative factors in hepatitis. A similar type of reasoning could also incriminate one of the our most popular and widely used beverages, alcohol. But with respect to infectious hepatitis it is now generally taken for granted that this malady is of viral nature. There is the additional fact that it has been the scourge of armies for many years and that it was especially prevalent in troops in World War II, before DDT and its associated pesticides had come into common use.

On the reverse side it is of interest that for the past two decades or more there seems to have been a definite decline in the incidence of cancer of the stomach in the United States. Although the reasons for this decline are still unknown, it is noteworthy that in Iceland gastric cancer is high on the list of causes of death. There Dungal has called attention to the high consumption of smoked fish and smoked mutton, and 3,4-benzpyrene has been demonstrated in sizable amounts in such meats. Whatever the reasons may be for the decline of cancer of the stomach in the United States, it is at least evident that there is nothing which points to pesticides in the American diet as contributing to this type of malignant disease.

Evaluation of Scientific Facts by Legislators Important

I hope it has been apparent thus far that my purpose has been to stress the idea that a great deal of medical misinformation now handed out so irresponsibly would be of little consequence were it not for the fact that it engenders increased pressures upon legislators. Inasmuch as most legislators are lawyers, and since lawyers have been rigorously trained in the evaluation of evidence, it would seem that if they could better know the truth about some of these questions they could save much time in committee hearings while trying to separate fact from fiction. In Washington there are always available sources of unbiased information, as, for example, in the National Academy of Sciences, the United States Public Health Service, etc., where congressmen could be briefed on problems in the medical and public health fields. If legislators could be equipped by contact with such sources to evaluate the scientific facts in relation to the half-truths of the fear-inspired writers, possibly they could judge more wisely with respect to specific legislation in its relationship to specific diseases.

Because of the possibility of a relationship between the use of food additives and the development of cancer, we in the Food Protection Committee initiated our studies on carcinogenesis some eight

years ago. At that time we assumed that such a study would require years of reflection and research. We did not anticipate the early enactment of legislation, at least until more adequate information about dietary carcinogenesis had been secured. However, legislation came in 1958 and 1960 in the form of the anticancer amendments. These amendments were controversial subjects at the time of passage, and they have continued to be such.

I believe it was Plato who said, "[T]he unexamined life is not worth the living." Possibly the same general thought may apply to legislation. In the case of the anticancer clauses, criticism is difficult because the humanitarian intent of the legislation is so evident. Moreover it can truthfully be said that the legislation has stimulated a great deal of important research in the field of carcinogenesis. Nevertheless after five years it is well to re-examine the situation in order to see if there is newer evidence of a lessening of the hazards of carcinogenesis in man.

It will be recalled that when the anticancer clauses were enacted, the principal points at issue centered around questions of fact versus speculation. Because of the paucity of facts indicating a proved relationship between the ingestion of carcinogens and the development of cancer in men, the legislation necessarily had to be based on hypotheses. These were: (1) the lack of proof of a dose-response relationship for carcinogens, that is, a threshold below which a carcinogen under test could be shown to be non-carcinogenic; (2) the possibility that ingested carcinogens might accumulate within the bodily tissues and react synergistically or by potentiation; (3) the chance that under certain circumstances even a molecule of a carcinogen might conceivably react with a singular cellular constituent to cause a mutation, thereby "triggering" the cancer mechanism.

The legislation was passed as a precautionary, preventive measure. In view of the lack of facts upon which it could have been based it is not surprising that there were those then, and there are still those, who would have preferred to have the individual, specific problems of carcinogenesis which might arise handled as matters of scientific judgment rather than as administrative decisions.

In the five years since the passage of this legislation some progress has been made in clarifying a few of the unanswered questions. There is possibly more reason now to believe that there are threshold limits below which certain carcinogens fail to elicit carcinogenesis experimentally. There is further evidence throwing doubt upon the

assumption that arsenic is a carcinogen. Unfortunately there is still no answer as to how far we can justifiably go in extrapolating experimental data to man.

In viewing some of these problems practically we are forced to assume the existence in man of some sort of dose-response limit with reference to carcinogenic action. Otherwise it would be pointless and futile to attempt to establish permissive dose limitations for radioactive fallout or for the use of x-radiation for diagnostic and therapeutic purposes. Similarly, despite the absence of evidence of a threshold limit to ultraviolet radiation in the skin of the mouse, it is assumed that in exposure of the human skin to sunlight there are several factors which determine its susceptibility to carcinogenic action. In practical matters of living, therefore, theory has to give way to practice under such circumstances.

In looking ahead to further problems connected with legislative efforts to minimize the dangers of carcinogenesis in relation to food additives, one wonders what our ultimate goal should be. Should we try to create an environment which is chemically pure insofar as suspected carcinogenic substances are concerned, somewhat analogous to an attempt to create a germ-free world? Are we sure that bodily tissues cannot acquire tolerances to minimal chemical insults through the agency of adaptive enzymes comparable in some measure to their ability to adapt immunologically to microbial agents of infectious disease? This is an area of pharmacology and toxicology which has been only partially explored.

But even if we can eliminate by legal means all such presumed hazards in relation to food additives or contaminants, what can be done about similar materials present naturally? For example, what can be done about the presence of selenium in wheat, about aminotriazole-like compounds in cabbage and kale, about saffrole in cinnamon and nutmeg, about products of fungal growth, such as the recently-discovered aflatoxins from the growth of Aspergillus flavus, in moldy peanut, soybean, corn and cottonseed meals, etc? Should legal measures be taken to stop the use of valuable protein supplements because of the possibility that in some of them mold products may exist which can cause the genesis of hepatomas in rainbow trout?

We in the Food Protection Committee are continuing to study these questions in the hope that ultimately more satisfactory answers may emerge. In the meantime there are reasons to suggest that the solution to these questions will lie more in the realm of scientific research than in the domains of legislative actions. **[The End]**

Scientific Bases for Food Legislation and Regulation

By FREDUS N. PETERS, JR.

The Author Is Former Vice President in Charge of Research, Quaker Oats Company, and a Member of the Food and Nutrition Board of the National Academy of Sciences.

SCIENTISTS AND GROUPS OF SCIENTISTS are much more a part of the Washington scene today than in the past, even though the foundation for science advisors to government agencies was laid in 1863, when President Lincoln granted a charter to the National Academy of Sciences. This group was charged with the responsibility of giving aid to anyone in government requesting help on science problems. Rather frequently, ad hoc committees have been suggested by NAS to assist Congressional committees and other departments of government. The Food and Drug Administration has used such groups on special problems of great urgency. However, there are two, more or less permanent, committees devoting all of their time to matters of concern to FDA. One of these is the Food Protection Committee and the other is the Committee on Cereals, both reporting to the Food and Nutrition Board of the National Academy. Outside of departmental personnel, no group of scientists has been in as close and continued contact with food and drug problems as have these two committees. It is appropriate, therefore, at this meeting marking the twenty-fifth anniversary of the 1938 Food, Drug and Cosmetic Act and five years of the 1958 Food Additives Amendment, that scientists from these groups look back and comment on some aspects of food legislation and regulations which are of most interest in their fields of specialization.

Doctor Cannon has discussed activities of the Food Protection Committee in areas where legislation and regulations arose at least partly as a result of medical misinformation and failure to obtain scientific evidence before action was taken. I shall comment on the effects of some regulations and proposed regulations on food research and technological development and raise a question as to the attitude

of the FDA toward acceptance of scientific data when they are available.

Food scientists are understandably eager to preserve their freedom of research and development and object to anything which curbs that freedom unduly. Almost 18 years ago, one of them charged that recipe standards discouraged research and could prevent technological improvements in foods. (F. N. Peters, Jr., 18 *Food Industries* 1180-2, 1316-28 (1946).) This charge was repeated by others with increasing emphasis over the intervening years. Upon passage of the 1958 Food Additives Amendment, many believed there was no longer any excuse for such restrictive standards. It is encouraging to note the action taken this past summer by the *Codex Alimentarius* Commission; a group established by the Joint Food and Agriculture Organization-World Health Organization Conference on Food Standards. (This Commission adopted a set of "Guiding Principles," one of which reads: "Unless clearly necessary, avoid 'recipe' standards, i.e., those which exclude the use of other than specified ingredients.")

It would be a constructive step if this was put into practice by our own FDA.

"Imitation Foods"

Another long-standing problem of interest to scientists, has to do with so-called "imitation foods." At times, a manufacturer is forced to use the denigrating word, "imitation" on a product having a distinctively different identity than the so-called original standardized product. Even though it be superior functionally or nutritionally, the word "imitation" may still be required on the label. A scientist can stand aloof from the frustrations of the manufacturer of such a product, but he cannot condone the suppression of technological improvements and denial to the public of scientific advances. Stated positively, a scientist would insist that any wholesome, honestly-labeled foods should have the right of trial in the market place, unhampered by derogatory names.

On June 20, 1962, a proposal for changes in dietary food regulations was published in the *Federal Register*. Some of these regulations fail to survive critical scientific analysis, and some appear to violate the principle of informative labeling which, I believe, scientists would support. Section 125.11 proposes that no mention can be made of the protein in a food except to say that it is a "good" or "excellent" source of dietary protein. In order to achieve a rating of good or excellent, the protein must attain a certain arithmetic score derived from a

mathematical formula containing a multiplier which is a function of "a reasonable daily intake of the food." There is no scientific basis for establishing any single figure as a reasonable daily intake. The age, sex, health, activity of the consumer, as well as other factors help determine the daily intake. Another multiplier in the formula is the AOAC Protein Quality Value. This value has not been generally accepted by qualified scientists and is still subject to change by the AOAC. As might be expected with such an illogical regulation, ludicrous results could arise from its application. For example, if a reasonable daily intake of egg is determined to be one medium size egg, then no claim for protein can be made. However, if it is a large egg, it becomes a "good" source of dietary protein, and if a reasonable daily intake is two eggs, then the product becomes an "excellent" source of dietary protein—yet in each of these hypothetical cases, the same protein is involved.

The proposal further does not permit even a statement of percentage of protein in the food, except on infant foods and those used in calorie-controlled diets. This prohibition of a factual statement regarding contents of a food not only reverses the long standing policy of FDA, but violates the principle of the consumer's right to receive full information.

It must have cost thousands of man-hours to develop these proposals, and industry spent some millions of dollars of man power commenting on them. Yet in the face of this prodigal expenditure of time on the part of FDA, it takes months or years to obtain action on the simplest of changes in food standards.

Enriched Corn Grits and Coated Rice Discussed

Two years ago, the Committee on Cereals proposed a change in the standard of identity for enriched corn grits to permit the use of a soluble premix instead of the prescribed insoluble premix. This proposal was discussed informally with FDA, and a formal resolution from the Food and Nutrition Board was delivered to the Department in the fall of 1961. For months there was no action. In the summer of 1962, a manufacturer of corn grits submitted a petition for a similar change in the standard. In February of 1963, the petitioner's proposal appeared in the *Federal Register* and finally in the late summer of 1963, the change became effective. (For similar cases, see Wayne D. Hudson, 18 FOOD DRUG COSMETIC LAW JOURNAL 54.)

For many, many years, the product known as coated rice (it carries a thin coating of glucose with a bit of talc to prevent sticking) has been sold in this country and Puerto Rico. Recently it has been gaining popularity in Hawaii. When a standard for enriched rice was promulgated, enriched coated rice was specifically omitted. In other words, vitamins and minerals may be added to polished rice, but it is illegal to sell coated rice carrying the same vitamins and minerals.

In April of 1962, the Committee on Cereals suggested to FDA that as long as coated rice was permitted, there seemed to be no logical reason to prohibit its enrichment. A formal resolution to this effect was submitted to the department. After six months or more had gone by, an interview with the person handling standards brought forth the statement that nothing had been done because Mr. Blank, a higher official in the department, was violently opposed to enriching coated rice and saw "red" whenever the subject came up. Six weeks ago, I talked to Mr. Blank and he was almost unaware that the matter was before the standards group and volunteered to learn why nothing had been done on the resolution submitted 18 months ago. As I left his office, I remarked that the Committee on Cereals carried no torch for coated rice, but as long as it was offered for sale, it seemed plain common sense that enriched coated rice also should be permitted. Mr. Blank replied, "I agree with you." Three days later he reported that an "interested party" would have to file a petition and prove that such a change in the standards would promote honesty and fair dealing in the interest of the consumer.

Nutritional Misinformation

Mr. Shelbey Grey, Director of the Bureau of Program Planning and Appraisal of FDA spoke in Atlantic City a few months ago to a group of business men. (18 FOOD DRUG COSMETIC LAW JOURNAL 505.) Some of his statements follow.

> You will probably be surprised to know that reputable members of the food industry are making significant contributions to the national problem of nutritional misinformation.

Then he listed five statements which he said usually mark the food quack and he continued:

> Need I call to your attention that the advertising and promotional approach used by some of our food manufacturers follow these same techniques? If you don't believe it, what do you think about statements that you can find on many food packages in the supermarket in this town, and in food advertising like "body building," "bone-strengthening," "energy-producing," "now enriched" "now fortified," "provides health," "high nutrition," "less calories per bowlful" "significantly greater in vitamins and minerals," "12 calories less per pat," and

"30 per cent more protein per spoonful." . . . [w]e believe they are definitely false and misleading!

It is unfortunate that such an intemperate and unsupported statement was made, because it benefits no one and can cause only harm to industry and the FDA. This statement can be quoted by quacks to support their claims that consumers cannot trust the reputable food manufacturers. It can be used by critics of the administration as evidence of dereliction, because if the label statements are false or misleading, the products are misbranded and subject to seizure.

But the scientist will ask—where is the falsehood—where is the nutritional misinformation in statements that a food is a "body-builder," "strengthens bones," "produces energy," is "enriched, fortified, high in nutrition?" It is not sufficient to answer that these statements alone are factual and the alleged falsehood lies in some undisclosed advertising context. Mr. Grey made the unqualified statement that he believed these words were false and misleading and contributed to nutritional misinformation.

And another question will be asked. Is the reputable food manufacturer to be denied the use of such words and phrases as "enriched," "fortified," "nutritious," "low in calories," just because they have been misused by quacks and charlatans? It should not be forgotten that a great deal of the consumer's recognition of the importance of vitamins, the value of good nutrition, the benefits of adequate breakfasts has come from advertisements, film strips, and consumer-education material prepared by the manufacturers accused of spreading misinformation.

"Less Calories Per Bowlful" Questioned

A bit of history regarding one of the phrases may be illuminating. Possibly it is not entirely unique. Objection was made to the phrase "less calories per bowlful." This statement was used in connection with puffed wheat. The idea back of these words and possibly even the exact words, were suggested by a nationally known and highly respected physician. He believed that this particular bit of information would be helpful to persons trying to maintain normal weight. His belief was based on a number of facts, as well as wide experience.

Per unit volume, puffed wheat has about half as many calories as most other ready-to-eat cereals. A bowl of puffed wheat contains about 50 calories, whereas a similar bowlful of wheat flakes would contain approximately 100 calories. Surveys show that persons serving themselves will tend to fill a cereal bowl, regardless of the relative

density of the food. Thus, psychologically, the public accepts a bowlful of cereal as a serving regardless of the weight. This fact is recognized by many diet charts and tables where a cereal serving is indicated as one ounce or 100 calories, except for puffed wheat or rice, where a serving is one-half ounce or fifty calories. Sometimes the unit is one cup. USDA Ag. Handbook, Number 8, Table 3 gives these figures for one cup: rice flakes—118 calories; wheat flakes—125 calories; puffed rice—55 calories; puffed wheat—43 calories.

Several years ago, I visited a Mr. X in the food and drug division, who had complained about the label statement, "less calories per bowlful." He said this statement was false and must be removed from the package, otherwise the product would be misbranded. The data, mentioned above, together with tables and references, were given to Mr. X, who then said that even if the statement was true, it was still misleading because a difference of 50 calories more or less in the daily diet was of no significance.

The American Heart Association, on May 26, 1959, sponsored a symposium on "The Prevention of Obesity," and speakers on that program stressed the point that effective weight control was best achieved by relatively small, but regular reduction of calorie intake. Fifty calories per day is equivalent to five pounds of body weight per year. One paper showed that a decrease of only 15 calories per day in hypothetical man made a decrease in weight from 175 to 160 pounds between the ages of 40 and 60 years. At the conclusion of the symposium, Dr. W. H. Sebrell, Jr., Director of the Institute of Nutrition Sciences, Columbia University, in summarizing the proceedings said: "If one is concerned with prevention and the treatment (of obesity) then it is necessary to reduce the intake by only 50 calories per day." (Reprint by Wheat Flour Institute from *Bulletin of the New York Academy of Medicine*, Vol. 36, Nos. 5 and 6, 1960.)

After seeing these data and hearing this statement, Mr. X merely said, "I don't believe this stuff and even if it is true, your label is misleading and you must remove the statement from the package." Now, two years later, the director of the Bureau of Planning not only repeats the statement that it is misleading, but says it is false.

It would be nothing short of tragic if a food and drug program should evolve in which zeal in support of personal opinions prevented careful examination of scientific evidence. Under such circumstances, it is difficult to envision the existence of any scientific bases of food regulation. **[The End]**

INDEX

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