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Food·Drug·Cosmetic Law JOURNAL

Concluding 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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FOOD DRUG COSMETIC LAW JOURNAL

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FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

This issue of the FOOD DRUG COSMETIC LAW JOURNAL contains the concluding papers of the 1963 Joint National Conference of the Food and Drug Administration and the Food Law Institute, Inc., which was held in Washington, D. C. on December 2, 1963. Except for the remarks made by William T. Brady, Chairman of the Board of Trustees of The Food Law Institute, the entire proceedings of the conference are recorded in the December 1963 and January 1964 issue of this magazine.

The President of the Food Law Institute, *Franklin M. Depew,* declares that it is time that both industry and the FDA reappraise their individual responsibilities. In an article appearing at page 9, Mr. Depew concludes that "under the best regulatory systems we have yet been able to devise, the public is largely dependent on the responsibility of business management. Complete government regulation is not economically feasible nor socially desirable. Therefore, it is only realistic to search for ways of assisting both government and management better to perform their respective functions in a cooperative effort for the benefit of all."

L. T. Coggeshall, Vice President of the University of Chicago, discusses the close working relationship that exists between universities and government agencies, especially the Food and Drug Administration. In regard to research efforts, he declares that "the FDA must call upon the assistance of the university scientist because both possess common long-term goals, both have skills to share, and the talent is too scarce to waste and the problems are too important to work apart." This informative article begins on page 12.

Continuing professional education in the field of public law is considered by the Dean of the Graduate School of Public Law at George Washington University. *Louis H. Mayo* advocates an expanded program in the area of the food, drug and cosmetic regulatory process in an article which begins on page 21. "Because of the changes in the scope of regulations which have taken place concerning foods, drugs and cosmetics, there seems to be an ever-expanding need for the offering of specific programs in the field of food and drug law which will equip attorneys and prospective attorneys to deal with the legal rights and obligations of the regulated industries. As is the situation with every law, in order for there to be proper administration, it is essential that not only the regulators, but those who are regulated, know the full extent of their rights, responsibilities and obligations."

"Proper public response to science, industry, government and education is essential if consumers are to have protection of their rights, and maintain or enlarge the sphere of protection given. This is the opinion of *Dr. Hazel K. Stiebeling,* in an article on consumer

(Continued on page 8.)

Loss of a Friend.—*Franklin M. Depew,* President of the Food Law Institute, made the following statement on learning of the death of an old and very special friend of the Food Law Institute, Mrs. *Harvey W. Wiley.*

"I report with sorrow the passing of Mrs. Anna Kelton Wiley, widow of Dr. *Harvey W. Wiley,* on January 6 at the age of 86. Mrs. Wiley had a long and distinguished career in support of many causes in the public interest and particularly in support of sound legislation and administration in the food and drug law field.

"It was my privilege to present Mrs. Wiley with The Food Law Institute's Outstanding Service Award on the occasion of our Dinner in honor of the Food and Drug Administration on December 2 last. Mrs. Wiley in accepting the award responded with her usual wit and good humor and seemed to thoroughly enjoy the evening's proceedings.

"I know you join with me in my feelings of gratification that we were able to honor and please Mrs. Wiley in this way.

"Funeral services [were] held on Friday, January 10, at St. Margaret's Episcopal Church, Connecticut Avenue and Bancroft Place, N. W., Washington, D. C."

Mrs. Wiley's late husband, Dr. *Harvey W. Wiley,* was instrumental in drafting the Pure Food Act of 1906.

A graduate of George Washington University, Mrs. Wiley was a member of the Citizens Crime Commission of Metropolitan Washington.

She is survived by a son, John P. Wiley, mission director of the Agency for International Development in Paraguay, and a granddaughter, Henrietta W. Wiley, of Washington.

AWARD FOR DISTINGUISHED FOOD LAW SERVICES PRESENTED TO MRS. HARVEY W. WILEY

In recognition of her significant contributions to a better understanding of Food Law by furthering the outstanding work in this field originated by her husband, Dr. Harvey W. Wiley, by cooperating with consumer organizations and the Food and Drug Administration, and by fostering cooperation between industry and public agencies, all of which were of outstanding service to the American People.

By

THE FOOD LAW INSTITUTE, INC.

December 2, 1963

Washington, D. C.

LETTER OF APPRECIATION

"Dear Mr. Depew:

"I write to thank you and the members of The Food Law Institute, most sincerely for the great honor bestowed upon me and Dr. Wiley by inviting me to that beautiful dinner on December 2, at Madison House here, and by giving me that eloquent and beautifully framed award, for the work I have done to advance the cause of pure food and drugs, over the years.

"I was greatly pleased and deeply touched by the great kindness shown me in bestowing upon me this beautiful award.

"The Award is now hanging in the dining room and I shall have pleasure every time I look at it.

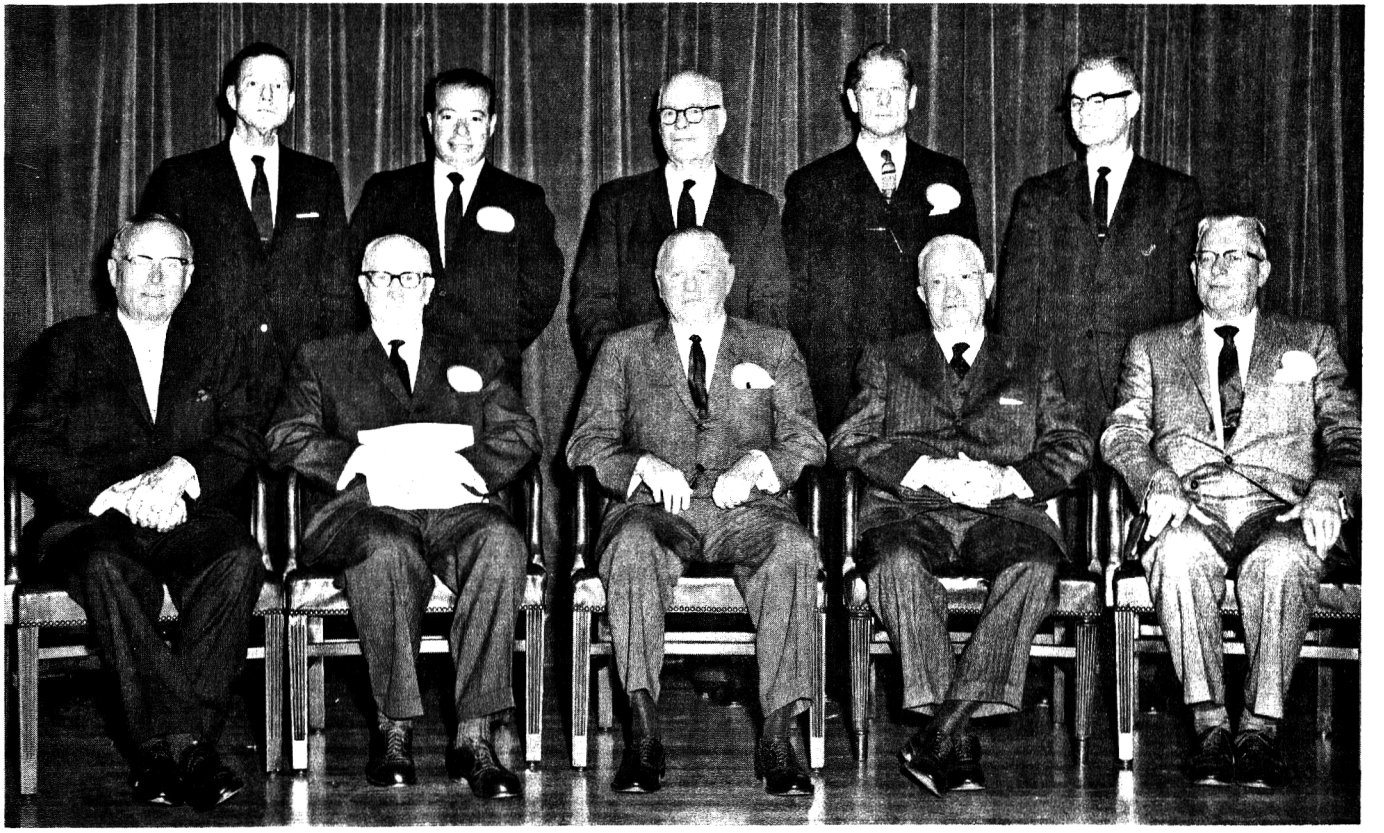
"May the Food Law Institute continue its valuable assistance to Dr. Larrick in the days ahead, in the cause of pure food, drugs and cosmetics, for the benefit of the public.

"I had the pleasure of knowing Mr. Charles Wesley Dunn and on several occasions I went to New York City to attend functions arranged by him. So I feel very close to The Food Law Institute and most grateful.

"Sincerely yours,
"Anna Kelton Wiley
"(Mrs. Harvey W. Wiley)"

Mrs. Harvey W. Wiley, shortly before her death, received The Food Law Institute's Outstanding Service Award from Franklin M. Depew, President of the Institute.

Anthony J. Celebrezze, Secretary of the Department of Health, Education and Welfare, is shown delivering the Welcoming Address at the 1963 FDA-FLI Joint National Conference. John L. Harvey, seated, was also a speaker.



Participants in the 1963 Joint National Conference of the FDA-FLI are shown in the above photograph. In the front row, from left to right, are: Paul B. Willis, Dr. Paul R. Cannon, William T. Brady, John L. Harvey and Franklin M. Depew. In the back row are: Edward Brown Williams, Robert L. Gibson, Dr. Fredus N. Peters, Jr., Dr. Theodore G. Klump and Winton B. Rankin.

(*Continued from page 3.*)
activities which appears at page 26. Dr. Stiebeling is a former deputy administrator of the Agricultural Research Services, United States Department of Agriculture.

Consumer achievements and opportunities are discussed at page 29, in a paper by *Edna Poyner,* program assistant, American Home Economics Association.

The Public Relations Director of the Cooperative League of the U. S. A., *David W. Angevine,* discusses "Our Rights and Responsibilities as Consumers," in an article appearing at page 37. Mr. Angevine, who is a member of the Consumer Advisory Council, Executive Office of the President, explains recent actions of the Council regarding pending legislation. He points out that consumers have certain responsibilities. The consumer must use the information to arrive at rational decisions in the marketplace, and this information must also be used to insure the consumer's safety. He mentions the responsibilities some consumers have accepted to serve themselves, as cooperative owners. Finally, consumers have the responsibility to organize politically, so that their influence will be felt in political arenas. Mr. Angevine's paper concluded the 1963 Joint National Conference of the Food and Drug Administration and The Food Law Institute.

FDA's Work.—*John H. Guill, Jr.,* Director of the Chicago District of the FDA, spoke at the recent Food Update Conference of the Food Law Institute in Chicago. In his concluding remarks, he offered this advice to the participants: "First, as a consumer, read the labels on all of the products you purchase and follow the directions carefully. Second, if the product offends you, tell us what the product is and why you object to it, permitting us to expand and intensify our effectiveness. Third, if you are a manufacturer or distributor, consider your product and your promotion of it carefully under the law and if in doubt of full compliance, submit your best effort with full information to the FDA headquarters or your district office for appraisal and comment before you begin distribution to the public." His informative paper is at page 47.

Advertising and Cosmetics.—*Charles A. Sweeny* discussed some considerations used in evaluating advertising for cosmetics before a meeting of the Society of Cosmetic Chemists. Mr. Sweeny, Chief of the Division of Food and Drug Advertising of the Federal Trade Commission, stated that self-regulation by industry and the individual advertiser is important. "The results would indicate that all too often the cosmetic chemist, who knows more about the products than anyone else, is the one person excluded from the advertising council." He urged the cosmetic chemists to take an active role in advertising in the paper which begins on page 53.

Consumers, Industry and Government.—This was the topic of an address given by *George P. Larrick,* the Commissioner of the Food and Drug Administration, before the fifty-fifth annual meeting of the Grocery Manufacturers of America, Inc. He cited communications, efforts to limit the occurrence of serious accidents, and the continuing need to develop closer relationships among all scientists concerned with food problems as matters of mutual concern. His comments begin on page 59.

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Food·Drug·Cosmetic Law
Journal

"A Time of Testing"

By FRANKLIN M. DEPEW

Mr. Depew Is President of the Food Law Institute.

THIS YEAR WE CELEBRATE the 25th anniversary of the strongest food and drug law in the world, the Federal Food, Drug and Cosmetic Act of 1938. The Food and Drug Administration has displayed an ability to adjust to new and burdensome duties which merits the respect and continued confidence of both the public and the regulated industries. I trust we are not unduly immodest in thinking that these annual conferences have been helpful to the FDA in so capably coping with these problems in this complex field. These meetings have furnished a vital means for strengthening essential communications between industry and government which in turn has been instrumental in bringing about a better mutual understanding of the problems in living up to the requirements of this important law—all of which has been in the public interest. We have accomplished much. But I shall not dwell on accomplishments, for both industry and FDA have been increasingly criticized in recent years. The times thus call for a new look at our responsibilities, if we are to overcome these criticisms.

We are meeting today at a time when the results of scientific research are straining our capacity to adjust to them without disavowing our deep-rooted beliefs that independence of action needs to be nourished and cherished and that our established system of freedom under law has fostered this independence. The problems resulting from the dangers inherent in newly discovered drugs on the one hand and from the confusion of consumers attributed to new methods of packaging and selling on the other have been troubling us in an increasing degree. That they may be solved without doing violence to the fabric of our present system of jurisprudence is of great importance to many of us.

I cite the following as examples of the efforts under way to deal with these problems:

(1) An Agency Coordination Study has been conducted by the Subcommittee on Reorganization and International Organizations of the Committee on Government Operations of the United States Senate, under the Chairmanship of Senator Hubert H. Humphrey. This subcommittee reviewed inter-agency cooperation in drug research and regulation, particularly as it related to new, experimental drugs. In Senator Humphrey's Background Statement with regard to the Exhibits compiled from August 1962 to March 1963, he said that he hoped the materials might pave the way for further sound decisions and actions in the public interest.

(2) The Drug Amendments of 1962 were enacted to strengthen the authority of the FDA in respect of new and experimental drugs as well as in other respects. The law and the regulations issued thereunder have been criticized by some in industry and the professions as putting undue restraints on research and development. If this is so, the law may retard, or prevent entirely, the discovery of new drugs needed to fight the diseases that afflict mankind. FDA held a conference on February 15, 1963 on proposed regulations under the law. Subsequently, some 37 drug firms challenged the new regulations covering labeling and advertising of prescription drugs. Many points of difference have since been resolved in government-industry conferences.

(3) The hearing record on the Hart Bill, S. 387, for a Packaging and Labeling Act, contains charges of many violations of the existing laws regulating the field of packaging and labeling. The Bill was disapproved in principle by the American Bar Association on August 15, 1963, on the grounds that it would delegate excessive administrative power to issue regulations without adequate standards, and that in consequence action might be taken which would unduly restrict freedom of private action for product improvements, variety of consumer choices, and purchasing economies. The bill has been reported favorably to the Senate Judiciary Committee whose further action on it is awaited.

So swift and revolutionary have been the advances in science and technology that have brought these problems into being that we are now faced with a challenge to our ability to adapt to them in a way which will best serve the public interest. The task ahead of us is an onerous and exacting one. However, faith in man's ability to adjust

to new problems offers an optimistic prospect of their due solution. I believe we can achieve that solution, if our legislators, administrators and industry representatives, act responsibly and cooperatively to that end. I especially stress the need for industry leaders to act with prudence and foresight. Such action is not only in the public interest, but in their own enlightened self-interest as well. This may involve taking appropriate legal steps to test the validity of regulations. It certainly involves making careful judgments on the propriety and legality of their products and labeling. Manufacturers can never tolerate violations on the ground that their competitors are doing the same thing. They must so carefully avoid any infringements of the law that even technical violations will disappear. If management does not devote itself to this task it may expect a public clamor for new legislation further restricting the public's and their own freedom of action.

Government Must Serve Public

On the other hand government must act responsibly, too. It must avoid making moves which are aimed at attracting the attention of the public rather than of serving it. It should correct industry abuses in such a way that the public does not suffer greater injury from the correction than from the abuse. No action should be taken as protecting the consumer without first weighing the relative values involved. It follows that government should seek solutions which will not stifle or discourage innovation and improvement in food and drug manufacturing. The problem faced by the legislative and enforcement branches of the government is avoidance of oversimplification—how to determine what actually does serve to advance the interest of consumers, industry and the national economy. This judgment requires a rejection of uncritical formulas. It calls for unbiased examination and consideration of all the facts in a search for the greater good—not just a consideration of how most quickly to still the complaints voiced about a particular situation.

In the final analysis, under the best regulatory systems we have yet been able to devise, the public is largely dependent on the responsibility of business management. Complete government regulation is not economically feasible nor socially desirable. Therefore, it is only realistic to search for ways of assisting both government and management better to perform their respective functions in a cooperative effort for the benefit of all. The speakers who follow me on this program will discuss how this may be accomplished. [The End]

The University and the Food and Drug Administration

By L. T. COGGESHALL, M. D.

Dr. Coggeshall Is Vice President of the University of Chicago.

THE ROLE OF GOVERNMENT in matters of public health of its citizens has been a constantly changing one. It grew slowly at first with the acceptance of limited quarantine duties and provision of medical care for the merchant marine. But the impulses in general welfare legislation have carried the interest of the government into far-reaching public health measures, into areas of education and research, hospital construction and patient care. It is in these areas that the universities and government formed a close working relationship, particularly in the past two decades.

It recognized early in this century that the individual states could not cope with problems now handled by the Food and Drug Administration.

After overcoming great resistance it was given long-needed authority to prevent adulterations, assure cleanliness and fight fraud in goods and drugs. A quarter of a century later, these powers were enlarged to encompass broader requirements for safety. And in another 25 years, a new task was given to the FDA. Beyond monitoring functions, it was given the assignment of passing on the usefulness of new drugs.

The evolution of the FDA shows how a policeman is becoming a professor. Historically, the stress was on prevention. Prevention is connected with punishment; wrong doers were punished as examples to restrain wrong doing. Then, in the late 1930's, the elixir of sulfanamide disaster occurred. A new law gave the agency more sophisticated chores. It was asked to rule on the safety of new drugs. To be sure, the assignment was phrased in negative terms: that new

compounds not be harmful. But such surveillance required new scientific standards and they were met.

How well they were met is best demonstrated by thalidomide. It was the old legislation and an unusual scientist working with it that stopped thalidomide from becoming the disaster in the United States that it became abroad. Under the old regulations, Dr. Frances O. Kelsey, who holds both the M. D. degree and the Ph. D. degree from the University of Chicago, exercised her talents and insights about this fateful compound. This reassuring act took place in the tradition of *prevention* in the Food and Drug Agency and in many ways typifies the best of that tradition.

Was Prevention Enough?

However, the threat of thalidomide produced great apprehension. Was prevention enough? The onward sweep of science was producing drugs of ever greater potency. In breaking the barriers of limited remedies, science in the past 25 years also has eliminated simple remedies. Modern medicines are indeed complex—in their concept, in their origins, in their operations. From complexity comes complications. With the advances in the new pharmacology, an old impediment revealed itself. This lay in the human mind, struggling with the limitations of predictability, of knowledge, of understanding. It is no wonder that the apprehensions stirred by thalidomide were real.

Two forces have been pushing the evolution of the FDA: the *law,* representing society's need and *science,* representing progress. The operation of these two forces can clearly be seen in the thalidomide episode. New legislation came with unexpected suddenness. Congress really intends that the producers do everything humanly possible and feasible to protect the patient. It placed a new charge upon the agency. Can it help pass upon the usefulness of a new drug? Will it help? Will it do what doctor and patient hope it will? Can it make things better?

University Becomes Important to FDA

Any medical practitioner, any scientist, indeed any lawyer, will immediately recognize such questions as being different from the old order. The shift is from a negative to a positive point of view. Before, there were "yes" and "no" questions: Is it toxic or not? Is it pure or not? Is it properly labeled or not? But now these questions

blur into more complex considerations. When someone asks, "How good is it?" we must begin to talk about the quality of judgment, not the rendering of justice. It is this quality of judgment that is new in the affairs of the FDA. The significance is clear—the change adds to the agency's administrative law role in the scientific community. It is in a scientific capacity that the agency must operate in its new sphere. And it is in this context here and now the university becomes more important to the FDA than ever before.

This may be new ground for the agency, but it is not new in government affairs today. Indeed, it is hard to tell science from government these days. The defense department has become a laboratory for weapons systems and captains of computers rank with captains of infantry. The post office is automating and the departments of commerce and labor are automating their research to study the problems of automation in the post offices and throughout our society. NASA is new science; agriculture is old science.

Fruitful Relationships Between Government Agencies and Scientific Community

There are many wholesome examples to fruitful relationships between government agencies and the scientific community. The National Acadamy of Sciences and its operating arm, The National Research Council, manifests one of the soundest and most productive relationships between government and science. The National Institutes of Health, the National Science Foundation, the Atomic Energy Commission, the Office of Naval Research—these and other agencies, all have worthwhile experiences that bear upon the immediate problems of the FDA. And perhaps the most striking contribution is the importance of the nation's universities and their scientists and scholars in assisting these agencies to carry out their scientific responsibilities.

The wellspring of scientific progress and talent in this country is the university. The scientific community extends far beyond the nation's campuses, but the scientific enterprises on those campuses constitute, in large measure, the source of the basic new knowledge whose rapid development characterizes our age. The university scientists themselves have been asked to take direct roles in the scientific councils and undertakings of the government in these perilous times. Their utilization has been so extensive, that in military terms, we are in danger of using up our reserves. The limitations are strin-

gent upon manpower presently trained and competent to participate in the many tasks related to government and the training process is slow, for the universities cannot relax their standards if they are truly to serve the nation.

However, it must be admitted that the close relationships with the universities and other health-government organizations did not apply to the FDA. There was no antagonism; there seemed to be no great need. Before 1963, few in university circles could have identified the FDA or would have expressed any continuing concern with its problems. Now, the situation has changed. There is a genuine feeling through the universities of this land of the reality of the scientific challenge facing the FDA. As the result of a major preoccupation with this problem during the past year I can state there is great concern plus a willingness to help. There should be no difficulty in obtaining necessary medical committees and the assistance of the most able men in the country.

It is true that the agency will have to give careful thought to its present role—both in discharging the new responsibilities and in working with university scientists. First, if Congress expects to get the improvement intended, the FDA must be provided with more staff, and adequate space and laboratories. Then it can carry out more effectively its expanded role. A level of scientific competence must be attained which will merit respect and cooperation from the scientific community. Because I am concerned that the nature of the new tasks may not yet have been fully appreciated, let me first restate them from a legal point of view:

"Quite clearly, these are not always matters of demonstrable scientific fact but rather in very many instances matters of opinion about which there can exist simultaneously honest differences. Assaying the role of arbiter of medical opinion will be a most demanding and difficult one for the FDA. It is fraught with perils for all. The concept of 'official or accepted opinion' is foreign to our science and one fervently hopes that it will always continue to be an alien view." [1]

Luther made these remarks at the Conference of Professional and Scientific Societies sponsored by the Commission on Drug Safety.

Or, if I may, let me state the problem from a personal point of view, drawing on my own experience in malaria research.

---

[1] James H. Luther, Jr., *Analysis of the Current Investigational Use Drug Regulations of the Food and Drug Administration.*

Malaria Cure

Malaria is a disease whose ravages have altered history. Until our era, there were two compounds that had considerable effect on the disease. Yet neither prevented, neither cured. And although both were in adequate supply during World War II, malaria was the number one disease enemy. Plasmoquin was discovered in the 1920's. It was highly toxic. Further, its efficacy was not of a high order. If judged on these grounds alone, this compound may well have been ruled out. But investigation continued. Several modifications of the molecular structure were achieved. They were successful. Prevention became practical and possible. So did cure. And today, the elimination of malaria on a worldwide basis is a reality affecting the course of history. No longer need we fear malaria as a severe war disease. The first obvious lesson from this example is not to let a potentially useful new drug, for instance, one effective against cancer, be assigned to the discard file prematurely. The first example of the eventual successful one is quite likely to be fairly toxic and relatively inactive.

FDA to Enter Scientific Process

The second equally obvious lesson is that the scientists of the FDA are going to have to become part of the scientific process to a much greater degree than before. Rather than remaining apart to maintain judicial independence, they are going to have to become more involved as participating scientists, fully aware of the ramifications, providing perceptive understanding of the decisions that must be made if progress is to continue. They bear a responsibility in helping make them succeed. I am reassured that this is presently the aim and plan of their leaders in the FDA.

And to return once again to the quality of judgment, this requirement means a continuity of professional relationships and integrity based on values shared with the entire scientific community.

The universities, of course, are aware that government involvement is a two-way affair. The government's presence on the campus is no longer either furtive or occasional. It's obvious. And it's there to stay. A significant portion of the curiosity served in the university laboratories is financed by government agencies. Graduate students look to federal support almost to the same degree that cadets in our national service academies do. The ivy has already climbed a considerable height on walls erected with matching capital funds from

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federal sources. When the government presence on the campus tends to pale, it is refreshed by the trips the faculty make to Washington.

Through all this involvement, the universities have remained, in large measure, true to their historic purposes and have not been grossly deflected from the pursuit of knowledge or the duty to impart it. With this confidence on the university side, the Food and Drug agency can, in its considerations, take confidence that its independence and special area of responsibilities will be respected as well as served. The response of university people to the thalidomide emergency demonstrates how strongly this point can be made. I can testify to the character of this response because of my association during the past year with the Commission on Drug Safety. Nearly 200 scientists—most of them from university positions—have participated in the Commission's efforts to bring together the best thought on the fundamental nature of the problems of modern drug testing.

Workshop on Teratology

One example of the many ways in which the government and universities can and must work more closely together in view of the new responsibility is a Workshop on Teratology (the science dealing with the maldevelopment of the embryo). It is being sponsored by the Commission. There was practically no evidence that therapeutic agents such as thalidomide when taken by humans would result in deformed infants. Even today, the mechanisms involved cannot be identified; hence, there are no reliable tests that can detect in advance similar episodes.

The Workshop will be held at the University of Florida in February, where 11 of the most distinguished scientists from the United States and Canada in this field will serve as the faculty in a 10-day session. The workshop will familiarize in excess of 60 participants and observers from government, industry, and universities with the concepts and methodology involved. In addition to the immediate practical value, I hope the more important long-term intangible results will be the stimulation of needed research in this neglected field. Regulations aimed at protection are impotent without adequate scientific data and facts.

The Commission's task is nearly done. It may be unusual in a society proliferating with organizations to report that the Commission on Drug Safety will go out of business when its final report is sub-

mitted next year, but that is the truth. The problems, of course, won't go away. In recognition of that fact, the National Academy of Sciences-National Research Council, as you know, has already instituted a committee to work in the academic traditional framework on the problems of new medicinal compounds.

Final Report to Commission on Drug Safety

The role and attitude of the university community is well-expressed in the final report to the Commission on Drug Safety by the subcommittee on the responsibilities of the universities in this field. It was prepared under the direction of the Dean of the School of Medicine of The Johns Hopkins University, Dr. Thomas B. Turner. The report reaffirms the critical nature of the research in new drugs which is undertaken by university scientists. It is this research on which the flow of new drugs, in preponderant degree, is based. It reflects the widespread response on almost every university campus with medical establishments that resulted in establishing groups of authorities to work on problems of drug safety. In fact, these new groups offer the FDA a ready structure on which to develop its new university relationships.

The report displays the attitude of the universities with recommendations that "universities be encouraged by financial and other support to continue basic research in the mode of action of drugs and the mechanisms of drug reactions."

In a recommendation to the pharmaceutical industry the subcommittee urged that the industry "work with universities in the development of clinical facilities for drug testing." The universities themselves were called upon to take a "greater degree of responsibility than at present for dissemination of information about drugs and drug reactions to practicing physicians."

Should the FDA and the universities cooperate on this one recommendation alone, a great service will be done for medical progress in this country. The communication channels are choked or nonexistent and this critical problem urgently needs research and performance, for information of importance to human life lies too often fallow and too soon forgotten.

Another recommendation asks the universities to give more emphasis to clinical pharmacology in the training of doctors. It proposes that "within the regular medical curriculum greater cogni-

zance be taken of the growing field of drug therapy and the importance of basic education of the physician in areas pertaining to this field."

In addition to the training of medical students and practicing physicians, the education of specialists in this field is a vital national need. The nation has 85 medical schools. A most conservative estimate would place the number of authorities in this area who could be of assistance in some role to the FDA at well below 1,000 men and women. In a nation of 180 million people whose health is increasingly dependent on basic pharmacological progress this is few indeed. The FDA must take measures to encourage the education of specialists in its field of special interest; perhaps fellowship programs will have to be developed by the agency to assure the nation of their development.

Government Research Expenditures Tapering Off

As the Agency steps into its new role, it will find that, in relation to the Congress and other governmental agencies, the climate favoring research will have changed from its pattern of the postwar years. The rising curve which has carried government research and development expenditures to the 15 billion dollar level is tapering off. In fact, it may fall from the heights of recent years. The Congress is asking a more detailed justification for each research dollar. Ironically, the university community, which perhaps is directly involved in less than one-tenth of the multi-billion-dollar federal Research and Development expenditure, is the most firmly established in demonstrating the integrity and the value of its type of research program. The FDA would do well to orient its scientific programs in such secure and productive ways, based on extensive and open cooperation with the nation's universities.

When the new regulations to enforce the new post-thalidomide law were put into effect, there was genuine fear in university circles as well as in other areas, that the scientific process would be impeded. The apprehension was not merely aimed at the added paper work as an additional bureaucratic intrusion, but to a larger degree expressed at the restrictions imposed on the qualified investigator. Dangers were raised that the quality of the scientific inquiry would suffer. The FDA through its scientific staff and program must demonstrate that the dangers do not exist. In contrast, it is called upon to show that masterful encouragement that leads to the solution of serious and

painful illness and ailment. It is asked to join, in the true scientific spirit, in the tasks of this modern era.

Conclusion

Thus far these dire predictions have not materialized. The FDA has a job to do and it is doing it well. It must not compromise on safety or fraud. But it must realistically face up to a greater responsibility of encouraging potentially new useful compounds with the same intensity it would seek to discard new harmless and ineffective compounds. Nothing must interfere with our research efforts. In this task the FDA must call upon the assistance of the university scientist because both possess common long-term goals, both have skills to share, and the talent is too scarce to waste and the problems are too important to work apart. I am confident the leadership is equal to the task and it will respond. **[The End]**

FEDERAL TRADE COMMISSION CALLS FOR CODE OF FAIR CIGARETTE ADVERTISING

In addition to proposing trade regulation rules for the advertising and labeling of cigarettes, the FTC has suggested the promulgation of a code of fair cigarette advertising as either a Guide or Trade Practice Rule. In a statement accompanying the issuance of the proposed trade regulation rules, the FTC said that this code of fair cigarette advertising would be intended especially to protect the youth of the nation against unfair or deceptive acts or practices in cigarette advertising. The extensive advertising on television on programs widely watched by young people, continuously projecting an image of cigarette smoking as a socially desirable and accepted activity, consistent with good health and physical well-being, may have a great impact on impressionable young minds, the FTC said.

In discussing the need for the proposed trade regulation rules, the Commission said that it has reason to believe that many current cigarette advertisements falsely state, or give the impression, that cigarette smoking promotes health or physical well-being or is not a health hazard. In addition, it said that much current advertising suggests or portrays cigarette smoking as being pleasurable or desirable, compatible with physical health, fitness or well-being, or indispensable to full personal development and social success. Such massive advertising depicting and constantly reiterating the pleasures and desirability of cigarette smoking, but failing to disclose the risks to health, appears to be a potent force in increasing sales of cigarettes, despite increasing scientific and governmental recognition of the existence and seriousness of the perils involved in smoking.

A public hearing on the proposed rules will be held on March 16, 1964, in the Federal Trade Commission Building, Washington, D. C. All interested persons, including the consuming public, may file written data, views or argument concerning the proposed rules. Twenty copies of such views must be filed no later than March 2, 1964. In addition, interested persons may appear at the hearing and present their views.

Continued Professional Education in Public Law

By LOUIS H. MAYO

The Author Is Dean of the Graduate School of Public Law at George Washington University.

IT WILL BE MY PURPOSE to consider briefly with you the matter of continuing professional education in the field of public law. Since we have had the satisfying experience at the George Washington University over the past several years of observing the growing interest of lawyers and of other professional people in the evolution of the food, drug and cosmetic regulatory process, I also wish to make a modest suggestion for an expanded program in this area. I do not purport, of course, to speak as an expert in this highly specialized area nor even as a professor of administrative law, but rather as a graduate school dean with an intense interest in the general field of public law. My comments, therefore, may more appropriately be directed to the broad administrative process than to an isolated segment of the federal regulatory scheme.

Apart from the question of political philosophy, we must take notice of a definite and continuing trend toward the enlargement of the executive-administrative function. This is a reflection of the growing number and complexity of activities within society and the need in many cases for some supervisory mechanism to police such activities, to resolve disputes, to inform the public, and to recommend changes.

The "Public Interest"

Since most of the modern administrative function has a relatively short history reaching back only to the 30's, (although food and drug regulation has a somewhat longer history) it is understandable why the agencies, the regulated industries, the practitioners and the independent commentators remain less than satisfied with both the adequacy of concepts and implementing practices. We continue to struggle with the meaning of the most basic concept of all, namely,

the "public interest." I would like to suggest to you that we not only need to rethink this concept and the mechanics by which it is reduced to operational terms, but that our general orientation toward this task should be revised. One of our major difficulties has been a tendency to think of the public interest as a static formula that can invariably be put in clear and exact terminology. This view reflects a basic human need for security and certainty and serves the highly practical need of agencies and practitioners for a workable level of predictability. Yet, we know that the public interest is by no means static, that except as an abstract proposition, the public interest must be thought of in terms of changing content. A significant implication flows from this assertion: if the public interest in every context cannot be defined specifically so as to serve the whole range of demands through an extended period of time, then it must be subject to continuing re-evaluation and restatement.

More Comprehensive and Effective Measures for Evaluation Needed

This proposition carries with it the necessity to introduce a device for evaluation and revision into the design of particular systems. This arrangement should provide a more effective way of satisfying the need for periodic re-examination than do spasmodic, *ad hoc* reviews lacking continuity and a sense of progression. The appropriate mechanism for this task will vary with agencies and departments and depend upon the particular regulatory function, the industry organization, and the impact upon the public convenience. Some agencies may find that an office of performance appraisal should be built into the regulatory structure. Others may feel that joint government-industry efforts are desirable, while some may wish to commission individual scholars or support a university-based program. Any continuing evaluation device selected will have some disadvantages. Nevertheless, the growing complexity of the regulatory process requires more comprehensive and effective measures for over-all and special agency evaluation than now provided. Such a program is needed to counteract the incessant tendency for the administrative process to deteriorate into an irrational and uncoordinated structure of administrative parochialism.

To give an effective degree of continuity to an advanced professional function, we have found that a modest program must be established with an interested director who can organize his activities

through a period of time, including course instruction, special conferences, publications and so forth. In this way maximum use can be made of past experience, and ideas can be collected, synthesized and selected concerning projected activities requiring highest priority for analysis and study.

Better Definition of Standards Urged

It is recognized that the concept of a continuously changing public interest raises complex problems of periodic adjustment of standards and procedures. It also tends to conflict with what many feel is the overriding need for bringing greater stability into the administrative process. Judge Alfred Friendly, for example, in a notable series of articles in the *Harvard Law Review* (1962), makes a vigorous plea for a better definition of standards. While his articles were addressed primarily to the regulatory agencies, certainly the theme is one which might have relevance to all agencies and departments engaged in administrative procedures. Of course, if either the concept of a continuously evolving public interest or the call for a better definition of standards is advanced with an unyielding insistency, this could give rise to a serious conflict of objectives. Perhaps through this clash the best available system would emerge. It would appear advisable, however, for reasons of economy of time, the adequacy of the resulting recommendations, and the maintenance of harmonious relationships among those involved that the matter be given deliberate, analytical treatment rather than permitted to degenerate into irreconcilable and damaging conflict. This is to say again that an immense opportunity exists for the re-examination of administrative law and related activities. Many informed criticisms in recent years have emphasized the unsatisfactory status of the administrative process in many respects. Relatively little is being done, however, in a systematic way to improve the situation. The prospect of a permanent administrative conference is welcomed. But universities, bar associations and the talents of individual scholars in law and governmental process are also needed to encourage and accomplish the work required in this complex field.

Common Problems

Exhortations concerning the general problems of the administrative process are of slight use, of course, in resolving the peculiar difficulties of individual agencies. Yet, despite the necessity for treating some matters of a given agency within their own specific

context, useful insights may be gained through comparative analyses of the procedures of the various agencies. Perhaps greater uniformity can be introduced even though reasons exist for distinctive treatment of certain matters within individual agencies. Some problems may be viewed in common focus: the distinction between adjudicative and rule-making procedures; the role of administrative discretion; the qualifications of and decisional techniques used by hearing examiners; the implications of the institutional decision; the question of burden of proof; and the obligations of an agency to keep the public informed of dangers associated with the products or services of the regulated industry.

Identifying characteristics of the types of educational programs in the administrative process field which will be required and will be developed within the next decade are now emerging. As activities expand, so does the accompanying knowledge. This means increased emphasis must be given to the selective process with respect both to the information coming to the focus of attention of professional personnel and to the content of programs of professional education. Continuing specialization to some degree is inevitable. At the same time lawyers, in all types of special areas, are finding it increasingly necessary to join with members of other professions in the analysis of complicated public policy questions. These factors emphasize two imperative needs: (1) continuing professional education for review of current developments and to provide insight into prospective developments; (2) sharpening the appreciation for modes of analysis of multivariable problems which can be dealt with only by an aggregate of persons having diverse skills and conceptual equipment.

It was with such considerations in mind that our Graduate School of Public Law was organized to provide a suitable vehicle for lawyers to treat public law problems in their total context rather than merely to isolate and analyze only their so-called legal aspects. Hence, lawyers are encouraged to acquaint themselves with the concepts and analytical techniques of others. Our program in Government Contracts involves lawyers, economists and public administrators. Our research into problems of law and psychiatry, the Federal Trial Examiners' Seminar, and such courses as "The Executive Function," "The Modern Corporation," "Use and Control of Atomic Energy," and "Labor Relations in the Federal Service" are means by which we enable students to consider important areas of public law in a cross-disciplinary forum.

Expert Legal Guidance Is Essential for Affected Industries

Quite relevant to the foregoing is the increasing degree of supervision exercised by the Food and Drug Administration over products subject to its jurisdiction in the course of the 25 years since enactment of the Federal Food, Drug and Cosmetic Act. In the past 10 years, a rather well-defined legal specialty has developed in this field which is comparable to that which has taken place in the fields of taxation and securities regulation. Further, the type of control exercised by the federal government in this area has gradually changed from a policing to a licensing system, as is evidenced by the development and expansion of new drug controls, antibiotic controls, pesticide controls, and food and color additive controls. Expert legal guidance is essential for members of the affected industries in order to comply with the requirements imposed. The role of the attorney in aiding the industries to insure compliance with these laws is no longer a sporadic one. Neither is it a simple one. Prospects are that additional legislation will be enacted which will further regulate the food, drug and cosmetic industries.

Because of the changes in the scope of regulations which have taken place concerning foods, drugs and cosmetics, there seems to be an ever-expanding need for the offering of specific programs in the field of food and drug law which will equip attorneys and prospective attorneys to deal with the legal rights and obligations of the regulated industries. As is the situation with every law, in order for there to be proper administration, it is essential that not only the regulators, but those who are regulated, know the full extent of their rights, responsibilities and obligations.

In this connection, assuming the substantiality of the array of problems presented in the Spring 1962 issue of the *Administrative Law Review* on "Procedural Techniques in Food and Drug Administration Proceedings," there is a special opportunity for the development of continuing professional programs in which the Food and Drug Administration, the food, drug and cosmetic industry, and selected universities might participate with valuable mutual benefit. Why not make this particular regulatory activity a model for the entire administrative structure?

In closing, I would like to pay my compliments to the Food Law Institute and particularly to Mr. Depew for the generous assistance provided law schools for the advancement of better understanding in this vital area of public concern. **[The End]**

Consumer Activities

By DR. HAZEL K. STIEBELING

Dr. Stiebeling, Former Deputy Administrator, Agricultural Research Services, United States Department of Agriculture, Introduced and Summarized the Remarks of the Two Concluding Speakers, David W. Angevine, and Miss Edna Poyner.

WE ALL ARE CONSUMERS, and would like to take pride in ourselves as smart, intelligent, and rational buyers and users of the thousands of goods and services that are available to our affluent society. But in our shopping, we find that the marketplace poses many problems that we are poorly equipped to face. It is hard to know whether this product or that will best serve our needs. In many instances we really do not know what we truly need or want, or what are the comparative values of the alternates from which a choice might be made. Too often we lack the technical knowledge that would enable us to ask the right questions, or even to interpret the information we are offered about a product.

It is little wonder then, that many people would be content to have a magic pushbutton that would tell them exactly what to buy without having to think about what they really need. Today's goods and the market situation are very complex. And so, consumers have to rely upon expert authority and public protection in the exercise of some of their rights. This is particularly the case in the matter of safety of foods, drugs and cosmetics. We must depend on scientific expertness and trained judgment to evaluate, regulate, and enforce production and inspection procedures that will permit only useful, wholesome and safe products to be offered in the market.

On the other hand, we do not want to relinquish any rights that we can and should exercise for ourselves. We want the abundance and variety of wholesome and useful products that modern science and technology can put on our markets. We also want the information that will enable us to make choices among them—choices that are in accord with our sense of values and our economic situation. We know that to whatever extent we exhibit ignorance or indifference, we may

fail to get full value and satisfaction from our purchases, and fail by just so much to achieve our potential level of living.

Proper public response to science, industry, government and education is essential if consumers are to have protection of their rights, and maintain or enlarge the sphere of protection given.

Consumers' Just Claims in the Marketplace

Right to safety.—For their right to safety, to be protected against the marketing of goods that are hazardous to health or life, consumers have to depend on government-industry cooperation for: (a) putting only safe and useful foods, drugs and cosmetics on the market; and (b) using scientific and technological advances for improving market offerings. On their side, consumers must be prepared to give the necessary support to this effort.

Right to be informed.—For the right to be informed, to be given the facts needed to make enlightened choices, and to be protected against misinformation, unscrupulous advertising, inadequate labelling, or other fraudulent, deceitful or grossly misleading practices, consumers have to depend on science, industry, and government to acquire and disseminate information about: (a) basic human needs for life, health and well-being; (b) the inherent values of foods, drugs and cosmetics on the market, how they may be used advantageously, and possible dangers from misuse; and (c) the quantity and the characteristics of goods in packages. On their side, consumers must learn to recognize valid authorities in these fields, be willing to learn, and then to practice what they know. For example, labels are useful only if they can be and are read, and if the information is put into practice.

Right to choose.—To be assured access to a variety of products at competitive prices, free enterprise is essential. Wise consumer choice in the marketplace is not a simple matter, however; it involves psychological and social wants as well as physical and physiological needs that must be satisfied within the economic means of the consumer. Therefore, consumers must become aware of the aspects of quality that are important to them in different situations, and how to recognize quality.

Right to be heard.—To be assured of full and sympathetic attention in the formulation of government policy, and that interested and informed individuals and organizations have a voice in these matters, consumers must earn the right. They must be knowledgeable about

issues, understand all the facts in the situation, and be realistic as to the implications of their recommendations as to costs and benefits.

Rights bring duties and responsibilities. This situation calls for continuous two-way flow of information between producers and consumers, government and industry, and science, government and the consuming public. All of us should strive for consumption patterns that are more satisfying to all of us, and redound to the public good.

[The End]

REVIEW OF FDA IN 1963

Industries inspected by the FDA voluntarily completed 2,047 corrective actions to improve consumer protection during the calendar year 1963. Included in this figure were 319 plant improvements at a total cost of $16,760,828 by food and drug manufacturers. The food industry voluntarily destroyed or converted to animal feed 23,950,886 pounds of food in 1,281 separate actions, where the products were found to have become unfit for human consumption.

The drug and medical device industries voluntarily destroyed products with an estimated total retail price of nearly 5 million dollars in 447 separate actions during the year. In all categories, voluntary compliance statistics showed impressive gains over 1962.

More than 63,000 inspections were made of food, drug and cosmetic establishments during the year. Inspectors collected 94,000 samples and FDA field chemists analyzed 86,000 samples to determine their compliance with the Federal Food, Drug and Cosmetic Act.

The educational value of an FDA sanitation inspection in assisting industry compliance is brought out by fiscal year 1963 records showing that reports suggesting improvements were issued to 6,608 food establishments, about one-fourth of those inspected. Inspectors prepare these reports and give them to an officer of the firm when insanitary conditions are found which could lead to violations.

Criminal prosecutions filed in the federal courts in 1963 totaled 214. Adulterated or misbranded foods accounted for 67 of these, while 184 were concerned with defective or dangerous drugs and medical devices. Of the latter, 135 charged illegal sales of dangerous drugs without prescription or authorized refill orders.

During the year, 29 injunctions were requested from the federal courts. Eleven of these were to prohibit shipment of illegal food items and 22 involved drugs and devices.

Food seized in 465 federal court actions totaled 6,996 tons. Other seizure actions included 278 drugs and devices, 70 hazardous substances and 2 color violations.

The total number of pesticide residue tolerances established since the Pesticides Chemicals Amendment of 1954 passed 2,600 during the year. About 130 pesticide chemicals are covered.

Many scientific advances were made during the calendar year 1963. A new and reliable method of identifying fresh and frozen skinless fish fillets by an electrophoresis test came into general use to prevent the palming off of cheap varieties for more expensive fish.

Consumer Achievements and Opportunities

By EDNA POYNER

Miss Poyner Is Program Assistant, American Home Economics Association.

I HAVE LONG KNOWN ABOUT THE FOOD LAW INSTITUTE and its conferences to bring together the leaders in law, government and the "public" to discuss the interest shared in problems that revolve around processing, marketing and consuming the nation's food supply. Through home economists who have addressed you, I am aware of the profitable interchange of information and am pleased to have this opportunity to establish a more than nodding relationship.

Today the consumer aware that he is being represented in more and more places is assuming more of his rights. Sometimes he does not choose to express himself and again he may be very vocal.

This interest in the "consumer"—the all-inclusive term that means you and me—has been of concern to many of us over a long period of years. The American Home Economics Association might claim the title of being the first organization to champion the cause of consumer interests. At least from the very first—at its organizational meeting in 1908—part of its program was devoted to the buying problems of the consumer. The interest and needs of the consumer have been a part of its program since that time.

Today our current program includes the following directives. We aim to:

(1) Inform and advise members about changes and developments in the consumer field.

(2) Provide current information and represent the interest of the consumer.

(3) Investigate and seek evaluation of questionable products and services.

(4) Develop effective means for educating the consumers to use all resources effectively and to assume responsibility for market conditions including action to correct detrimental practices.

Consumer Message

We were all proud when the late President Kennedy sent his Consumer Message to Congress. It was the first time in the history of our country that the consumer had clearly received executive recognition for effective consumer representation in the federal government. His message will continue to serve as a guide for the course and programs that are developed for the ever present needs of the consumer.

Immediately following the message, every department of the government appointed a person to act as its representative on an interagency committee. At the moment there is no way to evaluate the far-reaching effect of their activities. But it is safe to say that at the present time we are living in a period when the consumer's needs and views are being given attention. We know the awareness of the consumer is being recognized when the Food and Drug Administration finds it advisable to expand its Consumer Consultant program from a part-time activity to a full-time responsibility.

We know that the Department of Agriculture has long been an advocate of consumer rights and privileges—by providing scientific information that helps families and individual consumers select and use intelligently the goods and services of everyday living. This was demonstrated recently at a conference where requirements for pesticide regulations were reviewed and discussed. The meeting—of a technical nature to be sure—indicated, however, that the interest of the consumer was not overlooked.

European-American Symposium on Agriculture

A recent event which took place was the European-American Symposium on Agricultural Trade held in Amsterdam last month. This all-inclusive meeting had important implications for although the symposium was held primarily to discuss international trade, a part of the program was devoted to the interest of the consumer—and you know without the consumer there can be no international trade. As a participant on the program, I listened to many different points of view and became well aware that the voice of the consumer is important worldwide. There are no boundaries.

It is good that we all have different points of view. These are reflected in our programs to meet consumer needs and wants. We find it profitable to meet with leaders in government and industry to discuss problems of mutual concern. With this free exchange of opinion we then can return to our own organizations and approach the various ways which best suit the needs of the consumer.

From time to time representatives from the American Home Economics Association meet with representatives of other national organizations to discuss programs and procedures beneficial to the consumer. Of course many associations and organizations have been leaders in developing effective consumer programs. Together these organizations put forth a valiant effort in behalf of the consumer. To mention only a few—the American Association of University Women, Consumer Council on Information, General Federation of Women's Clubs, AFL-CIO's consumer program, and the Consumer's League. There are others that would come to your mind.

Importance of the "Unwritten Assurance" to Consumer

We are all familiar with the fact that the consumer has an awareness that laws have been made to protect him. He is aware of an "unwritten" assurance about the food he buys on the marketplace. This leads him to expect that his food is safe, wholesome and nutritious. Although technical legal language may baffle him, science and technology, wisely administered, give him confidence.

The consumer continues to demonstrate his awareness and confidence in the law by readily accepting new food products streaming into our marketplaces.

Research carried out in the United States Department of Agriculture, state experiment stations, colleges and universities, and food industry laboratories has found the answer to many important questions, and in so doing has contributed to safer more wholesome food for the consumer.

Through our research, we continue to know more and more about the components of food and about the type of additives that help to improve and protect foods. Science, through industry, helps the consumer to know that the food he buys is safe and clean, by bringing the consumer food attractively and conveniently packaged in clear transparent bags.

The consumer wants everything concerned with his food safe. He expects this to be so.

The public, as well as the retailer, is upset and disturbed when it is reported that caution must be taken about certain food products and rightfully so. We do not want anything to interfere with our security.

Consumer's Safety Is of Prime Importance

I am thinking of the most recent problem the FDA faced—the outbreak of botulism. For the most part, I believe the mass media handled this information fairly well. A food product rich in protein on which the livelihood of many persons depends must maintain acceptance. There should be an awareness of the dangers involved, but not an over-emphasis. We are fortunate in being able to control our food supply so that an outbreak such as this can be quickly checked. Safety is of course of prime importance.

Not only does the consumer expect his food to be safe, but he wants it to meet quality standards wherever he buys in today's mobile living. This in itself poses a problem since the distribution of food regulated by federal law does not automatically apply to intrastate commerce. Obviously, it hardly seems fair to the average consumer that food standards that meet the requirements of interstate commerce do not apply to intrastate commerce and thus do not offer the same protection.

It should be recognized, I believe, that laws pertaining to food in the United States at the federal level are made for *all* the people.

States differ in their laws pertaining to food; for example, we find standards of identity that apply to food differ from state to state. Are consumers aware of this? How many consumers do you think are aware that enrichment of bread is now compulsory in only 28 states? It is estimated that about 60 per cent of the white bread in this country is enriched. In am sure that many consumers assume that all the bread is enriched.

Consumers Look for Standards of Identity

Over the years the consumer has been accustomed to look for standards. This word is a familiar one—one that makes him comfortable. He knows that this term assures him a certain quality in the items he purchases. He can, if he wishes, get the exact information which covers a certain standard.

A standard is a symbol of protection. With our increase in technical information on the development of food products, new methods of food preservations, and new ways to market products in a more

acceptable form, some of the standards formulated are no longer applicable. The orange juice standard recently revised would serve as an example.

A standard gives the buyer a measure or, to say it another way, a means of enabling the processor, the retailer and the buyer to speak the same language. In general, a consumer has no conception of what is involved in formulating a standard. He could prove to be of greater assistance than he has been in the past. This is one of his responsibilities that he has not assumed. If he would extend his energies and direct his reactions, he could express what he has observed concerning these products in the marketplace. This would make him a more discriminating buyer.

Some manufacturers, producers and advertisers would have us believe that standards present obstacles which curb initiative, better marketing practices and stifle research. On the contrary, experience over the years has proved that the consumer who with confidence can purchase a properly labeled product to meet specifications is the satisfied consumer and continues to be so.

For instance, a product which is properly labeled and meets consumer satisfaction, will be the one purchased if available in any area. All of us know that the shopper does not always make her purchases in only one supermarket. Why? Because no one management can offer *all* the brands of standard quality which are available to the consumer. We often travel long distances to shop for our needs.

Standards Should Be Established for Fresh Fruits and Vegetables

Not only in the area of processed foods do we need standards, but in this era in which we live, a real source of joy to the homemaker are fresh fruits and vegetables. These, too, should meet standards. The handling of these items to insure the highest nutritive content when purchased needs further attention. Unless foods are properly handled at the point of shipping, even modern methods of transportation do not give the consumer the wholesome nutritious product it was intended that he should have.

Before a standard can be published, a great amount of investigation and research is necessary. We are aware of the problems that confront government in bringing together the necessary parties to be heard, and the careful consideration given to all of the evidence that has been presented. Here, too, those representing the law often offer delaying tactics. Standards to be effective should be formulated

within a reasonable length of time. May we suggest greater cooperation by all concerned—industry, consumers, government and the legal profession, to give the consumer his rightful protection.

Informed Consumers Advocated

As home economists we have always believed in consumer education. One of our leaders, Dr. Helen Canoyer, Dean of New York State College of Home Economics at Cornell University, and Chairman of the Consumer Advisory Council, had this to say about consumer education:

> It is my conclusion from a good many years of experience in the fields of economics and home economics, that the basic problem underlying all so-called "consumer problems" is the lack of education. It is not enough, in fact it is impossible, to represent consumers in a meaningful way if they are ill-informed and irresponsible. It is not enough to offer them isolated pieces of information about specific problems if they do not have a broad framework of understanding about their role in our economy as responsible consumers and citizens.

We recognize that it is important in today's world to look to informed leadership. The home economist is concerned with bringing to the homeowner—who is a consumer—the right kind of technical information, and at the same time preserve and restore the main sources of human motivation and decision. She helps the consumer to adjust to changes and new discoveries.

Consumers need sound information on which to base sound judgments—for judgment cannot be better than information. The basic scientific information that comes from research must be interpreted for the consumer. For example, research conducted by the Human Nutrition Research Division of the United States Department of Agriculture, when interpreted, helps to guide the consumer in her selection of foods in the marketplace. The channels of government, industry and consumer organizations are available to the consumer so that he may obtain the right kind of information, based on scientific fact. At the same time, we must build the vigorous programs to keep misinformation about foods from the consumer.

Effects of Misinformation Can Be Harmful

After all the years that home economists here and around the world have contributed to the basic fact that calories *do* count, I wonder how any author would find it lucrative to publish a book that *Calories Don't Count,* but one did. I guess our work is never done! So, from this illustration it seems that misinformation has a greater

appeal to the consumer than sound technical information. The process of education of the public is a never ending one.

Misinformation can affect the health and well-being of the American family for years to come and at the same time have its ill effect upon the economy of our country. For example, in 1962 well-meaning, but unqualified persons spread the word that milk and milk products were contaminated with strontium $_{90}$ and should therefore be severely restricted, if not completely curtailed. Knowledgable persons became so concerned with this misinformation as to cause the United States Public Health Service to warn the public against such unwarranted claims.

We can readily see the serious effect this could have on our infant and child population if, without professional guidance, parents simply eliminated milk and milk products from the diets of their children. The health of the whole nation could well be jeopardized. This information is confirmed in an article published in *Military Medicine*, August 1963. We have constant responsibilities to combat misinformation.

Responsibilities of Home Economists

Yes, the consumer has rights and responsibilities, but he needs to be made aware of what these are. Our role is to help the consumer recognize his responsibility and avail himself of the efforts being made in his behalf. The American Home Economics Association continues to find effective ways and means of helping the consumer solve his problems, increase his knowledge, and assume his rightful place in contributing to the health of the nation.

As home economists, we recognize the responsibilities that face us. One of our many responsibilities is to work for informative labeling. Consumers have a right to know what is in their food. Labels should be free of extraneous material so that important information is easy to read. Consumers should know what information they can expect to find on the label. This basic information about each product should be easily accessible.

There are home economists, the dietitians, who are particularly concerned for they need certain information on the label in order to make their work more effective.

In the dietary field, dietitians have a responsibility to work for the best possible labeling of dietary foods. The home economics

nutritionist has a great contribution to make in the revision of labeling of dietary foods.

And in all of this—getting this information to the consumer is a responsibility of all home economists—particularly the home economics teacher. It is important to teach students—in high school, college, and university—about consumers and the food and drug field —and the revolution in our kitchens from home-cooked to processed foods.

Through our efforts to influence the well-being of families, we deal face to face with the problems that confront the proper growth and development of human personalities. We know the average homemaker—a consumer—is intelligent and thoughtful and that she is as much interested in quality and performance as in cost. She wants freedom—freedom of choice. She knows that the underlying principle of buymanship and objective facts about food must become a part of her and that her judgment reflects the quality of education which makes her a responsible consumer. Even though the educational process is a slow one, the consumer needs knowledge which leads to sound judgment based on fact.

The consumer should become aware of the progress the Food and Drug Administration is making in its very difficult job, and the contribution made by the food industry and by government to bring to the consumer the finest food supply this country has ever known.

Response to changes and new discoveries comes through creative leadership. The challenge to improve the education of youth and adults has never been more vital. This is no time to run away from the problems that confront us. We need the help of all who are concerned. We need to keep the consumer constantly informed of the rapid pace of technical advances.

We need more help from the legal profession, government and industry. We need to find ways to use this technical knowledge to help the consumer to recognize and accept his responsibilities.

[The End]

Our Rights and Responsibilities as Consumers

By DAVID W. ANGEVINE

The author Is Public Relations Director, Cooperative League of the U. S. A., and a Member of the Consumer Advisory Council, Executive Office of the President.

I AM DELIGHTED to be here today to discuss the rights buyers have and the duties we incur in the marketplace. It is there that buyers face sellers, and it's this relationship of the marketplace that confers rights and imposes responsibilities on both parties, however impersonal the transaction there may be.

Forty years ago Dean Roscoe Pound explained that our substratum of law rests on relationships—the relation of master and mechanic, of lord and tenant, of mortgagor and mortgagee, of borrower and lender. These relationships, the "tendency to affix duties and liabilities independently of the will of those bound," represents "the first solvent of individualism in our law," Pound said. "Rights, duties, and responsibilities" arise "not from express understanding, (or from) the terms of any transaction, (or from) voluntary wrongdoing or culpable action, but simply and solely as incidents of a relation." "Duties and liabilities are imposed" on a manufacturer, processor, or retailer in his relation to the customer "not because he has so willed, not because he is at fault, but because the nature of the relation is deemed to call for it." The rights and responsibilities of consumers spring from this "fundamental mode of thought," this "mode of dealing with legal situations."

Consumers' Just Claims in the Marketplace

Buyers have spoken of their rights for decades. Yet it remained not for a lawyer, not for an economist, not for a consumer spokesman to collect, to systematize, to classify these rights. It remained for a

President of the United States. Twenty months ago President Kennedy declared the consumer's right to safety, his right to be informed, his right to choose, and his right to be heard. I want to emphasize not the particular words of the President's unprecedented consumer message to Congress. Rather I want to emphasize the significance of this effort by the highest official of our land to codify the rights that everyone of us has when he enters the marketplace.

In time we may realize that consumers, as a matter of right, have other just claims, and we will add these to those the late President stated. We may amend those four rights or expand upon them. But whatever we do, we shall always go back to this point in time—to President Kennedy and this statement to the 87th Congress. In 1962, after more than a half-century of turmoil in the marketplace and conflict between buyers and sellers, the President stated what the consumer holds as a matter of right.

Three-quarters of a millennia ago, out of turmoil and conflict the English nobility found words to express their just claims against the sovereign. Nearly 200 years ago, a few score colonial representatives found words to express what they felt were their just claims to "life, liberty, and the pursuit of happiness." And now the late President has put into words consumers' just claims in the marketplace—the rights to safety, to be informed to choose, and to be heard.

One thing we know is that these rights—or any rights—must be enforced if they're to mean anything at all. The rights specified in the Great Charter weren't secured until the British Parliament enacted them into law. The words of the Declaration of Independence achieved reality only through the Bill of Rights, the laws of Congress, the decisions of the Supreme Court, and the enforcement machinery the President and his administration has available.

So with the rights of consumers. These four rights are widely recognized today—even by those who offer no more than lip service to them. But they are not universally accepted. When the tuna fish you buy is contaminated, when the TV commercial that invades your home is deceptive, and whenever you face Hobson's choice in the marketplace, your rights as consumers are violated. It means for us to clothe these basic rights with the substance of law.

Our late President said the consumer has a right to "the facts he needs to make an informed choice." It has been my pleasure to work the past year and a half as a member of his Consumer Advisory Council, and much of what we've done relates to facts for consumers.

S. 750—Truth-in-Lending Legislation

For example, we advised President Kennedy to support Senator Paul Douglas' truth-in-lending legislation (S. 750). We see this as a chance to clothe the consumer's basic right to be informed with the substance of law. It will give consumers the facts we need to make rational choices regarding the use of credit. If the bill is enacted, we will know before we borrow or before we commit ourselves to an instalment contract how much we must pay in financing charges, expressed both in dollars and as a simple annual rate of interest.

With this information, a consumer can choose rationally between buying a product today when he doesn't have the purchase price and buying it later when he has saved the money. Under this bill, the consumer would have the data he needs to balance immediate satisfactions against larger future satisfactions. With the proposed information available to him, the consumer could also compare credit costs and shop for the least expensive credit.

Rational consumer choice in this field would protect ethical and efficient lenders—who fully disclose their credit charges—from unfair competition of those who practice deceit and concealment. It will reinvigorate price competition in consumer credit, and as consumers choose less expensive credit, they'll expand their effective demand for goods and services. The legislation will help consumers become aware of rising credit costs in boom times and declining credit costs during recessions, and their decisions may introduce a new, stabilizing element into the nation's economy.

S. 387—Truth-in-Packaging Legislation

The Consumer Advisory Council also advised the late President to support truth-in-packaging legislation (S. 387). In this too we see the opportunity to clothe the consumer's basic right to be informed with the substance of law.

In the past three years Senator Philip Hart has listened to the widespread discontent with packaging, labeling, and pricing practices as they prevail in the modern supermarket. And because he is a shrewd listener, Senator Hart has been able to devise ways the government can assure consumers of the facts they need to make more rational decisions in the shopping center.

I'm sure I don't need to spend time here detailing the packaging and labeling sins of industry which deny consumers the opportunity for rational choice. Prophets of persuasive skill have called business-

men to repentance, and I have no illusion that I could succeed where they have failed.

Let me, therefore, simply mention fractional-ounce containers which make it impossible—without a slide rule or other equally intricate device—for consumers to determine the per-ounce cost of tuna fish, potato chips, or washing powder. And let me recall the package that looks bigger than it used to but contains less. And the package whose statement of net contents is effectively hidden from all but the most determined buyers. And the soap that carries no statement of net weight because it somehow slips outside the definitions and is not a food nor a drug nor a cosmetic. And the slack-filled container. And the meaningless designations of package size that foul the channels of communication as the consumer attempts to make a rational choice. On supermarket shelves now is a 12-ounce "medium size" bottle of salad oil. A friend of mine who has spent 17 years in the food business says he never saw a smaller bottle of salad oil than the new "medium size." And finally let me simply recall watered ham—which wasn't labeled as watered ham. Food retailers tell me ham sales still haven't recovered from this controversy. (While Senator Hart's bill would not apply to meat and meat products, the Consumer Advisory Council feels it should.)

Such labeling and packaging practices effectively deny consumers the opportunity for rational choice. When President Kennedy stated the consumer's "right to choose," he spoke of "access to a variety of products and services." Yet unless choice among this variety of products can be rational, can be based on reason and objective evaluation, then the right to choose is meaningless.

Industry can halt those practices which, from the consumer's viewpoint, have created chaos in the supermarket. Through the simplified practice and commercial standards procedures of the Department of Commerce, businessmen can eliminate much of this confusion by voluntary agreement. Yet, as the Consumer Advisory Council has pointed out, industry hasn't used this machinery and instead has continued to expand those practices "which impede intelligent consumer choice."

I'm continually amazed at, say, the peanut butter manufacturer who cries, "Over my dead body," whenever it's suggested that his product should be packed in half-pound, pound, and 3-pound containers. Now, peanut butter differs. Some is homogenized. Some is "old-fashioned." Some is crunchy. It comes in refrigerator jars and

beer steins and jelly glasses. And consumers will consider these differences in making their decisions.

But why is this big peanut-butter man unwilling to have his product compared on a per-ounce-cost basis with competing products? Does he know he can't stand the competition? Is he saying, in effect, that he's such a high-cost, inefficient producer of peanut butter that if he's forced to offer consumers information so they can easily compare prices he'll be out of business? Does this man really prefer to trust the fate of his product to the composers of TV jingles than to the rational judgments of United States consumers? The parade of industry witnesses who have testified against Senator Hart's truth-in-packaging bill would make one think so.

The President's Consumer Advisory Council feels we need this legislation to make a rational, intelligent choice. The bill will also, we feel, promote honest competition, protect consumers against fraud, and help our economy function more efficiently.

This legislation involves no added long-term costs. Indeed through greater standardization, it holds great hope for long-term cost reductions. As the regulations are issued over the years, some firms will experience certain conversion problems and inconveniences that increase their short-term costs. Consumers will pay these—just as they pay industry's other costs. Whether these have been overstated to the Senate subcommittee I don't know. Perhaps no one does. So far, however, they don't worry me.

As I said, we know that rights—if they are to mean anything at all—must be won. Simply to express them is not enough. The rights of consumers must be backed by legislation, such as the truth-in-lending and truth-in-packaging proposals, and by the enforcement machinery of government.

Consumer's Interest and Producer's Interest Different

Another thing we've learned from the common law concept of rights as an expression of relationships is that sellers aren't buyers, that merchants aren't consumers, that the man who offers goods for sale isn't the man who buys them. This may seem elementary, but it's worthwhile stopping for a moment to realize that this idea of relationships, on which both rights and responsibilities are founded, establishes a polarity of interests. The consumer's interest and the producer's interest are different. They may be equally matched. They

may be coterminous. They may even be complementary. But they are not the same.

Just as we cannot expect the landlord to watch out for the interests of the tenant, and just as we do not depend on the employer to protect the interests of his employees, just so we do not expect vendors to promote the interests of their customers. All the fine statements urging consumers to rely implicitly on the tender sentiments of merchants and manufacturers is pap—and nothing more. For the interests of consumers and the interests of this nation's corporations are not the same.

Unquestionably landlords have built many fine homes that serve their tenants well. Employers have paid high wages to their workers. And businessmen have created a magnificent array of serviceable products that enhance the American consumer's living standard. But these things they have done to promote their own interests—not the interests of consumers. To bring forth a new product or a better product or a less expensive product, a businessman's primary goal must be increased profits, not the consumer's interests. If it is otherwise, he risks failure as a businessman.

To be sure, the same course of producer action sometimes serves the interests of both the consumer and the producer. We should constantly seek to multiply the instances when these interests parallel each other and, when they do, to seize such opportunities. But these interests are not the same. They are different.

Consumers' Responsibilities

This brings me logically to our responsibilities as consumers. For if sellers cannot be expected to guard the buyers' interests, who can? And the answer, of course, is the buyers themselves. We consumers have the responsibility for promoting our own interests, and we have the responsibility for using such techniques as are available to us.

First, we have the responsibility for using the information—which we are entitled to as a matter of fundamental right—to arrive at rational decisions in the marketplace. Only in such way can consumers reward the wisest and most efficient use of labor, capital, and natural resources.

Apparently businessmen don't expect consumers to make rational decisions. Or they don't want them to. For the fact is they do a great deal to thwart the exercise of judgment.

For example, impulse buying is, I take it, the opposite of rational choice. As you know better than I, advertising men and merchandisers exert tremendous effort to stimulate impulse buying. They fight for larger packages on the supermarket shelves and more shelf space for their product. They design labels, packages, and brand names so as to entice the unwary purchaser. They probe sex symbols and daydreams. And the purpose of all this is impulse buying.

I take it, also, that irrational appeals are the enemy of rational choice. As a consumer, industry expects me to buy a particular cigarette because it tastes "like a cigarette should," or because—believe it or not—of "the wonderful, wonderful world of softness." One manufacturer tells me to buy a particular whisky because "the first taste will tell you why." A new synthetic fabric is a good buy "because there's a new kind of warmth." The producer wants me to buy a soft drink because it contains "a kiss of lemon, a kiss of lime." (While I like being kissed twice, I'm afraid this leaves mostly carbonated water.) And I'm told to get a particular cold tablet because it contains "the ingredient doctors recommend." (Since this ingredient remains nameless, I suspect it's aspirin.)

These subjective appeals are calculated to induce consumers to purchase merchandise for spurious reasons. Their purpose is—as my colleague, Dr. Richard Morse, says—commercial mesmerization. These appeals are irrational, and they contribute, I'm sure, to the growing irrationality in our society. No longer are consumers expected to have cogent, logical, satisfactory reasons for our decisions in the marketplace. And what is worse in a democracy, this irrational attitude carries into the political arena. When we behave irrationally, hatred and bitterness follow.

Somehow, the consumer must see through, or ignore, or overcome these irrational appeals, for he has the responsibility to make rational decisions. To some extent, he does so already. I believe he will do so to an increasing extent in the future. We have few formal channels for the consumer to gain skill in buymanship. These we must expand. I believe we will. Already consumers respond to increasingly frantic efforts to woo our purchasing power with a towering disbelief. The American Association of Advertising Agencies study released last spring found consumer "indifference," "skepticism," and "much discounting of individual ads"—even of the ads they could remember.

The consumer's second responsibility, being so like unto this, I I mention only briefly. He is responsible for using the information—which is his right—to assure his own safety. It's unthinkable that we should ban rat poison, simply because some thoughtless parent sometime might let his offspring get hold of it. If a label clearly warns, "Keep out of reach of children" or "Keep away from open flame," it's the consumer's responsibility to obey.

Responsibility Through Cooperatives

Third, I want to mention the responsibility some consumers have accepted to serve themselves. Through cooperatives, 14 million United States families own the supermarkets, service stations, apartment buildings, furniture stores, pharmacies, farm supply stores, credit agencies, electric utilities, hardware stores, health clinics, and insurance companies where they get the goods and services they want. Back of these lie a number of consumer-owned factories, refineries, oil wells and electric generating stations.

These consumers have accepted the responsibility for operating these businesses in their own interests. They provide the capital, establish the policies, elect the directors, pay the taxes, and divide up what's left at the end of each year. In the food business we're pretty small. There are only 53 consumer-owned shopping centers that have passed the million-dollar-a-year mark. Nevertheless, these include the largest supermarket in Chicago and nine in suburbs of the nation's capital.

Fortune magazine says the businessman is "scientist, artist, inventor, builder, and statesman." Concentrated industrial power, with so few men making the big decisions, denies most men the chance to exercise these talents. Through cooperatives, however, these millions of consumers have claimed that opportunity. It is for many of them an almost daily exercise in freedom.

As more and more consumers accept this responsibility for meeting their own needs, they can begin to establish sovereignty over this nation's economic life. At present consumers are engaged in a continuous referendum on such products and services as businessmen choose to submit to them in the market-place. With their dollars, consumers vote "yes" and "no," and they thus exercise tremendous economic influence. They have the power to dispose.

Economic initiative, however, remains in the hands of producers. They propose. Consumers buy or refuse to buy what industry believes

it is potentially profitable to produce. Consumers don't announce their wants. Instead they wait for manufacturers to uncover such wants as it is profitable to supply.

We've had enough experience with certain types of cooperatives to know that they can offer consumers full sovereignty. Credit, electricity, and insurance are outstanding examples. Through credit unions, production credit associations, and federal land bank associations, consumers have devised savings and lending services that best meet their needs. Before consumers accepted this responsibility, such services didn't exist. No producer was willing to offer them. And though today these consumer-owned credit institutions have many imitators, they keep the initiative they acquired 30 years ago.

Through electric co-ops, rural consumers accepted responsibility for providing themselves with the kind of service they needed and could afford. Commercial utilities generally weren't willing to take the risks, though now that this type of service has proved successful, these firms are eager to buy up the co-ops.

Through insurance co-ops, consumers devised a number of types of coverage that other firms generally felt couldn't be offered at prices that consumers would pay. Today these policies are standard throughout the industry.

Finally, consumers have, I believe, the responsibility to organize politically—not in any partisan manner, but to exert their influence in the political arena. The silence of the consumer in Washington and in the capitals of most of the 50 states is notorious. For too long the consumer has relied on the "countervailing power" of giant producer interests to assure his welfare. Increasingly, consumers realize they must look out for themselves.

I presume this reflects the growing preoccupation with consumption. For a while we know we can produce all we need in our society, we're quite uncertain whether we can find politically acceptable ways for us to consume what we produce. The consumer's growing self-awareness is reflected in the surging circulation of *Consumer Reports* (now over 800,000). It's reflected in a million-plus circulation of *Everybody's Money*, a quarterly that first appeared less than three years ago. And so on.

Our late President has clearly stated, for all time to come, those rights which are ours as consumers—rights which are ours, not because of any corruption among producers, not because these rights are

written into a specific contract, not because consumers have won them in the Supreme Court, but rights which are ours simply because we are consumers. It is tremendously important at this moment in history for this nation to clothe these rights with the reality of law, even as our President suggested 20 months ago. This is a political duty that falls upon us, and I am confident consumers will not shirk this responsibility. It has been a real pleasure for me to be here today and to outline briefly these rights and responsibilities, as I see them.

[The End]

PRESCRIPTION DRUG ADVERTISING REGULATIONS PUBLISHED

The Food and Drug Administration has announced publication of regulations controlling drug advertising. Regulations issued last October became fully effective January 13. They spell out the manner in which information must be presented in prescription drug labels and advertisements, so as to insure a balanced presentation of the facts regarding the drug advertised.

Effective in 90 days is a regulation published January 10 with regard to the supporting data which will be required for advertisements of "old drugs." (FOOD DRUG COSMETIC LAW Reports, ¶ 3405.)

As originally proposed, this regulation would have required that advertisement for old drugs, as well as for new drugs, be supported by "substantial evidence" that the drugs would have the effectiveness advertised.

Substantial evidence of effectiveness is defined in the Kefauver-Harris Drug Amendments to mean evidence obtained through adequate and well-controlled scientific investigations.

The point was made by the drug industry that some old drugs, long in use in medical practice, had substantial clinical experience to support their claims, although they have not been subjected to the kind of controlled clinical investigations that are needed to support the claims for new drugs.

Under the revised regulation, FDA will accept adequately documented clinical experience to support the advertising claims for old drugs. Industry objections have been withdrawn. The revised regulation will become effective in 90 days.

As revised, the regulations permit the advertising of these old drugs for uses "for which there exists substantial clinical experience, adequately documented in medical literature or by other data (to be supplied to the FDA, if requested), on the basis of which it can fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses."

The regulations require prescription drug advertisements to present information concerning side effects and contraindications for uses recommended or suggested in the ads and for any other use or uses for which the dosage form advertised is commonly prescribed. There must be a fair balance between the desirable and any undesirable effects of the drugs.

The Work of the Food and Drug Administration

By JOHN H. GUILL, JR.

The Director of the Chicago District, Food and Drug Administration, Delivered This Address at the Food Law Institute Food Update Conference in Chicago on November 5, 1963.

THE FOOD AND DRUG ADMINISTRATION is a consumer-protective enforcement agency of the Department of Health, Education and Welfare. Other prominent Health, Education and Welfare Department agencies are the Public Health Service, the Social Security Administration, the Office of Education, and the Welfare Administration.

In 1955, the Food and Drug Administration was studied intensively by a group of distinguished citizens, the first Citizens Advisory Committee. It made over 100 recommendations. One of the most significant was that we were woefully understaffed to do the job Congress had assigned to us and we should be expanded three to fourfold in the next five to ten years. We have been working on this. In 1956 we had approximately 850 people; this year's budget authorizes more than four times as many. Meanwhile, however, our responsibilities have grown materially with the passage of the Food and Color Additives Amendments, the Hazardous Substances Labeling Act and the Kefauver-Harris Drug Amendments of 1962.

Approximately 40 per cent of our people are in Washington serving as our administrators who establish the policies of the organization and set the proportion of our time we usually spend on various industries. The administrators also receive information and consider the recommendations from the field offices and other sources. Also in Washington we have many expert scientists. They do basic research in many areas, develop and test methods of analysis and serve as our expert advisors on scientific matters.

The remaining 60 per cent of our people are distributed in 18 field offices located in the principal cities of our country. A typical district

has about 120 people—three to four are administrators, 50 to 60 are inspectors, 35 to 40 are chemists, 15 to 18 are clerks, and the remainder are aides who assist the inspectors and chemists.

Three Major Functions of FDA Inspectors

The inspectors have three major functions. They go to the various types of establishments operating under the six laws we enforce and physically examine the building, the raw materials, the equipment, the manufacturing procedures, labeling and storage facilities utilized in producing the food or the drug or the cosmetic being studied. They are seeking to detect violations in this operation.

The second inspectional duty is the collection of official samples. These are collected representatively from a large lot or as large a lot of the product as we can find in interstate commerce; usually we deal at the wholesale level. The samples usually are generous, amounting, for example, to two to four cases of various types of, let us say, canned goods, depending on how much is present. We usually examine about half of the sample and hold the remainder available during the period of interest, as required by law, for anyone who can establish a legitimate connection with the goods as shipper or claimant. The inspector must document the interstate movement of the product by copying the transportation record, the invoice or bill, and determine what people have first-hand knowledge of the identity of the product and the records.

Our inspectors also make investigations. These are frequently complex and almost always lead to the making of an establishment inspection or the collection of a sample.

The Chemists' Role

Our chemists have the primary job of analyzing the samples for whatever violation is suspected, such as excessive pesticide residues, filth from insanitary production, or other foreign or undeclared components. They may exercise their curiosity after checking for the suspected violation and examine for a violation they may suspect. About 10 per cent of the chemists' time is devoted to the development and testing of methods of analysis.

Our inspectors and chemists are college graduates. The inspectors must have had 30 hours of science in their curriculum, while the chemists must have 30 hours or more of chemistry to qualify. We are actively seeking competent employees in these categories and urge that anyone who is basically qualified and interested contact our

Washington or district offices. A Food and Drug Administration career is interesting, varied, public-protective work.

The clerks do the typing and filing and maintain our other records so that information is readily available when needed.

We enforce six laws; however, the two most important ones are the Hazardous Substances Labeling Act passed in 1960 and the much amended Federal Food, Drug and Cosmetic Act of 1938.

Enforcement of this latter law consumes most of our time and energies. It forbids the interstate shipment or the carrying in interstate commerce of an adulterated or misbranded food, drug, device or cosmetic. It also forbids the receipt of such a product after shipment in interstate commerce and, furthermore, prohibits the doing of any act with respect to a food, drug, device or cosmetic which has been received from an interstate source which would result in these products becoming adulterated or misbranded. This last section applies frequently to small repackers who purchase products in bulk which come to them under simple but correct labels. The product is repackaged into smaller containers and labeled with misbranding claims which violates the law.

The Federal Food, Drug and Cosmetic Act carries a maximum penalty on conviction of $1,000 per count and/or a year in jail for the first offense and for a second offense or fraud three years in jail and $10,000 per count.

Eight Procedures FDA Uses to Achieve Compliance

While we must have a strong penalty section to deter violations, we have a total of eight procedures through which we try to achieve compliance. The first is through education. Talks such as this help. We will talk free of charge to any industry group composed of members from more than one firm or to practically any group of consumers.

Also under education, our field district offices, our Division of Public Information and Division of Advisory Opinions in Washington answer many consumer inquiries daily by phone and letter. Whenever anyone has a new product or proposes new uses for a product, it would be wise to send the formula and a rough draft of all of the proposed label and all of the proposed promotional material to our Division of Advisory Opinions for its constructive comment. These laws are quite complex, but they are public and it is the duty of those in businesses affected by them to comply. However, we are glad to

assist with this comment when full information is provided on the proposal.

The second method is comment by the inspector to responsible members of management during his factory inspections. The law requires our agent to give a written notice of his intention to inspect. Immediately after issuance, it is illegal to refuse to permit his inspection. We are also required to leave a receipt for materials gathered during an inspection and if we observe insanitary conditions or practices, we must leave a written statement identifying them. Our more experienced inspectors will comment on obvious label defects; however, most labeling problems are complex and require the study and response of our experts in Washington.

The third method is by letter. The law provides that in the incidence of a minor violation, the Secretary may call it to the attention of the particular firm or individual by sending a letter to this party. This is occasionally done.

In method number four, citation, we write in plain English to the firm or individual citing the provisions of the law violated by a specific product. We set a day and time for the party addressed to come to our office for an informal discussion of his views concerning his product under the charges. The party addressed may ignore the notice, write a letter of response, send a friend, his attorney, or come himself. Such informal hearings permit a discussion of the charges and frequently result in effecting compliance.

Method number five is a public protective measure which involves seizure of goods that are adulterated or misbranded. These actions are brought through the Department of Justice on evidence submitted by the Food and Drug Administration. People having a demonstrable legal interest in the offending product may appear as claimants and, in the event of a contest, a jury trial of the charges may be held in federal court. Frequently the offending product can be reconditioned or relabeled and be legally restored to interstate channels of trade.

Method number six is prosecution. This action is taken against firms and persons who violate the law significantly. These actions move rather slowly because of the many reviews of the evidence made in our organization and in the Department of Justice before the charges are filed publicly with the federal court. Each case brought has five such considerations and some may be studied by as many as seven sections before the case is filed. Any of these reviewers may

stop the case. Thus you can accurately conclude that any prosecution action filed on FDA's request is believed by us to represent a significant violation and to be a serious matter.

Method number seven is the injunction provision of the Food, Drug and Cosmetic Act. It is used against those who cannot be effectively curbed through seizure and/or prosecution. An injunction consented to or applied by the court amounts to a court order not to violate the law any more. If violated, the action is contempt of court. In this situation the penalty on conviction is set at the discretion of the court.

The eighth method concerns conspiracy. Whenever two or more people connive to violate a federal law they may be charged with conspiracy. The penalties on conviction are usually heavy.

If you encounter any product which offends you and you believe it is one under our jurisdiction, we would appreciate your reporting it to us by phone or by letter. If you believe you have been injured and you plan to bring suit against those responsible, we cannot participate in your litigation. Nevertheless, we need to know the details of your experience in order to protect the rest of the public from a similar injury. We need to know the name of the product, its manufacturer or distributor as shown on the label, the code, if any, on the package, and where you obtained the product, as well as the nature of its deficiency.

The American food supply is the most abundant, wholesome and nutritious in the world. Most of our producers and manufacturers strive continually not only to maintain the high standards they have helped to set, but also to improve upon the cleanliness and wholesomeness of their output. Most people who violate the law are unaware of their transgressions until we call them to their attention. Then they are usually eager to bring their product into full compliance. We encourage this procedure rather than resort to court action for each infraction. As mentioned before, we urge all shippers of products under our jurisdiction to submit their labeling and formulas to our Division of Advisory Opinions in Washington for comment designed to avoid their violating the law.

Diet Study of a 19-Year-Old Boy

Late last year Food and Drug Administration reported the findings on a total diet study it has been conducting in five cities across the country. Foods such as the ordinary middle income family would

use are bought in the retail grocery stores just as you and I would buy them. The vegetables, fruits, meats and dairy products are prepared in the customary manner for serving. Portions of the size which would be consumed by a 19-year-old boy are removed and analyzed. This 19-year old is the heaviest eater of our populace. He consumes 55 to 60 pounds of food and drink per week. Analysis of these portions of food show that generous amounts of protein, fats and carbohydrates are present. All of the vitamins and minerals needed for healthful nutrition are there to excess. Occasionally some pesticides were detected; however, the amounts present were infinitesimal, way below the tolerances set for these substances on the raw agricultural products. The amount of radioactivity was found to range from 10 to 25 per cent of the amount suggested by the Federal Radiation Council as an acceptable health risk for large general population groups.

I believe that our food producers can take pride and that as consumers, you can find comfort in this knowledge that our ordinary foods are safe and nutritious and that one need not supplement his diet with costly special doses of vitamins and minerals if one is well and consumes an ordinary varied diet of the readily available foods.

Now I want to leave you with three thoughts. First, as a consumer, read the labels on all of the products you purchase and follow the directions carefully. Second, if the product offends you, tell us what the product is and why you object to it, permitting us to expand and intensify our effectiveness. Third, if you are a manufacturer or distributor, consider your product and your promotion of it carefully under the law and if in doubt of full compliance, submit your best effort with full information to the FDA headquarters or your district office for appraisal and comment before you begin distribution to the public. **[The End]**

Some Considerations in Evaluating Advertising for Cosmetics

By CHARLES A. SWEENY

The Following Remarks Were Made by Charles A. Sweeny, Chief of the Division of Food and Drug Advertising, Federal Trade Commission Before the Society of Cosmetic Chemists Meeting in Boston on September 24, 1963.

I AM COMPLIMENTED to be invited back to speak to a meeting of the Society of Cosmetic Chemists. I feel this especially, as the lone attorney appearing on this program of scientists speaking your language and directly sharing your daily experiences.

I am here as a staff member, speaking for the Division of Food and Drug Advertising rather than the Commission, with a discussion of our attitudes toward advertising. But, after all, I hope I will not get far away from the subjects you are discussing today. The Federal Trade Commission has no new statutory responsibilities, but it is appropriate at this time to review some trends in application of old ones.

Drug and cosmetic safety, as well as effectiveness, is a matter of real concern to the Commission. The Wheeler-Lea Amendments of 1938 were occasioned largely by a desire to curb the advertising of harmful products. It was for this reason that Commission authority in respect to advertising for foods, drugs, devices and cosmetics was substantially broadened.

The Commission was authorized to seek temporary injunctions prohibiting advertising pending issuance of an administrative complaint and order to cease and desist, when this would be to the interest of the public. Prompt action to curb advertising for a harmful drug or cosmetic obviously is to the interest of the public. Furthermore, the Commission was empowered to institute criminal proceedings if the product advertised may be injurious to health. One section of the amendments directed the Commission, in determining whether an advertisement is misleading, to take into account the extent to which the advertisement fails to reveal material facts.

As a practical matter, the Federal Food, Drug, and Cosmetic Act now precludes the sale, over the counter, of drugs and cosmetics which are inherently harmful. But a product which can be used safely in accordance with the labeling may be misrepresented in collateral advertising, with respect to safety as well as effectiveness. In our staff consideration of advertising, we begin with the assumption that any proprietary drug or cosmetc can be used safely in accordance with labeling contraindications and directions. Therefore, when the word "safe" appears in an advertisement we have even more reason to look closely at the manner of its use.

Misleading Claims of Safe Use

In some instances, there may be affirmative advertising claims for safety which are categorically and literally false. In addition, we at a staff level are looking closely at advertising which represents, for example, that a product is safe when taken in accordance with directions. This means to the consumer (and we base our attitude upon letters of complaint we are receiving, as much as upon a grammatical construction) that anyone and everyone can use the product safely if he follows the directions. "Directions," to the consumer, means dosage recommendations, cautions against excessive use, and so forth. The consumer is misled when he is told that anyone can use this product safely if he follows directions, if he gets home with a purchase and finds upon reading the labeling, that he is one of a category of persons who should not take the product at all. He is shocked to learn that he cannot take the product safely in accordance with any directions. Here we may not put in issue the actual safety of the product —simply the deception which results from advertising which says that a person can use it safely and labeling which informs him that he cannot. There is nothing subtle or unique about application of the law because the advertising obviously has misled him into making his purchase.

We are also questioning advertising which may not contain affirmative false claims, but which violates the statute by failing to reveal material facts—by conveying an impression which is misleading because material facts are withheld.

Vitamin Deficiency Claims

One product area in which we have proceeded and are continuing our attention is that involving vitamins. The Commission has issued

cease and desist orders[1] which hold that advertising for vitamin products to treat tiredness and other symptoms ascribed to vitamin deficiency must:

(1) Expressly limit claims for effectiveness to persons whose symptoms are due to an established deficiency of the nutrients supplied, and

(2) Clearly and conspicuously disclose (a) that in the great majority of persons these symptoms are not due to a vitamin deficiency and (b) that in such persons the product will not be of benefit.

This same doctrine of express limitation and affirmative disclosure may well be applied to other nutritional supplements offered for therapeutic purposes.

We are now attempting a still further disclosure in advertising for iron supplements. It is our staff belief that if such a product is effective in relieving anemia or its symptoms, in doing so it may mask bleeding from some serious disease or disorder and thereby permit its progression; and that these are material facts which should be disclosed in the advertising. We are at this time litigating a case presenting this issue.[2] When all of the pertinent evidence has been developed in the record, it will be considered by the Commission. I must emphasize that until then I am stating only a staff position, and not one established by the Commission.

Our efforts to require affirmative disclosures, when they aid in avoiding deception, are based upon that provision of the Federal Trade Commission Act[3] which specifically directs that in advertising for food, drugs, devices and cosmetics, consideration be given to the failure of an advertisement to reveal facts material in the light of the claims made, or material with respect to consequences which may result from use of the commodity.

Thus in respect to nonprescription drugs, the Federal Trade Commission may in the future require that advertising reveal more of the possible harmful results from use of the preparation, including side effects and contraindications. It may also extend requirements for affirmative disclosures of limitations on effectiveness. Such extension, under the Commission's present statutory authority, will be

[1] Docket 8150, *Lanolin Plus, Inc.*, TRADE REGULATION REPORTS, ¶ 16,077; Docket C-123, *Hudson Vitamin Products, Inc.*, TRADE REGULATION REPORTS, ¶ 15,854.

[2] Docket 8547, *J. B. Williams, Inc., et al.*, TRADE REGULATION REPORTS, ¶ 16,213.

[3] Section 15, TRADE REGULATION REPORTS, ¶ 25,267.

limited by and based upon the need for such disclosures to prevent deception of the consumer.

As scientists, you may be interested in knowing how we approach and consider advertising claims based upon scientific propositions. Our approach is neither mysterious nor any more elaborate than the situation requires. The physicians and other scientific experts on the staff of the Commission's Division of Scientific Opinions work as a team with our attorneys in investigating these cases and throughout the trial.

Our attention may be drawn to advertising in any of several ways. Our alert monitors may detect and forward a questionable advertisement to an attorney for examination and discussion with one of our doctors. A disappointed purchaser may report that the product failed to perform as claimed. A competitor may challenge the representations in a well-documented complaint.

FTC's Procedure

Regardless of the manner in which an advertisement comes to our attention, our procedure is the same. Assuming that the necessary jurisdictional requirements appear to be present, our question is whether the public is being deceived. If we are to take action, we must be prepared to establish by persuasive evidence that the advertising is misleading, and this generally means proving that it is false.

The medical member of our lawyer-scientist team is charged with responsibility for this phase of the case. It is his duty to review the literature, discuss the issues with experts, arrange for clinical or other testing as appropriate, and produce qualified witnesses whose testimony will effectively support the case.

As a part of our investigation we are, more and more, addressing orders to advertisers directing them to submit special reports revealing, in effect, their basis for advertising representations. These orders are individually authorized and issued by the Commission itself and failure to comply therewith subjects a respondent to severe penalties.

The orders require the advertiser to submit material pertinent to the claims he has made, including the formula for the product together with directions for use and, of particular interest here, copies of all reports and other data concerning tests of the preparation and memorandum opinions relating to its efficacy. The purpose of this

demand is to aid in our effort to learn as much as possible about a product, enabling the Commission to make an informed determination as to whether representations are sufficiently questionable to warrant issuance of a complaint.

We are frequently asked to explain our standards for evaluating clinical tests. Our standards are no more nor less than you as careful investigators would require. We are concerned with the design of an experiment and whether it has been performed correctly; whether there were a significant number of tests; whether the results were recorded accurately and are internally consistent and coherent; whether the results warrant the conclusions drawn; lastly whether the conclusions when translated into advertising claims have been expressed in a meaningful, accurate way so that consumers lacking scientific training will understand without deception.

Glamour Theme in Advertising Cosmetics

While I have not been referring directly to cosmetics in this discussion, this is because the Commission's authority and procedures with respect to advertising for cosmetics are precisely the same as for foods, drugs and devices. However, we encounter one factor more commonly in the cosmetic field than in the others. This is advertising with the glamour theme, where it is difficult to distinguish between legitimate puffery—glorified sales talk which no one believes literally—and substantive representations which are believed and relied upon. Certainly, for example, no cosmetic could long exist without promising increased beauty. We are not likely to challenge the claim.

While there has been little publicity concerning Commission activity in the cosmetic field recently, this does not mean that we dismiss it lightly. We are reviewing the advertising every day. Much of it is being considered more carefully by our attorneys and doctors.

Some of these matters are being discussed with advertisers and corrections in advertising effected informally. As no complaint is issued in these instances there is no public record and no publicity.

It may be significant to mention, however, that in one instance [4] recently the Commission issued a complaint and order prohibiting representation that a preparation would prevent baldness or cause hair to grow.

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[4] Docket No. C-249, *Beecham Products, Inc.*, TRADE REGULATION REPORTS, ¶ 16,121.

You are certainly familiar with the long line of Commission decisions holding that in the usual case of baldness nothing will stop hair loss or regrow hair. I am sure you as chemists will agree with the findings.

I cannot help but wonder what your personal reactions are to the cosmetic advertising we see every day in every medium. How do you feel about television commercials? As experts on the subject, do you resent proceedings by the Federal Trade Commission? Do you believe it is overly sensitive in its actions to protect the public? I think not. But what part are you playing in the development of this advertising? Can you consider yourself in a world apart—completely divorced from the promotion of your creation? Should you develop a product which is safe and suitable for a beneficial purpose and not be interested in whether the advertising exaggerates or misrepresents such safety and usefulness?

The cosmetic chemist in industry has a very definite role in preventing false and misleading advertising, with respect to safety as well as effectiveness. He, probably more than anyone else, knows best just what a product will do, and its limitations, its side effects, its contraindications.

Regulation of advertising is not a game between government and industry, with laws and regulations as its rules. The purpose of advertising is simply to inform the public about products available to them, permitting them to select a product which meets their needs. It can be stated just as simply that the purpose of Federal Trade Commission regulation is to see that the advertising describes and refers to the product in such terms that the purchaser gets what he has been led to believe he is buying.

Self-regulation by industry and by the individual advertiser is the first step. The results would indicate that all too often the cosmetic chemist, who knows more about the product than anyone else, is the one person excluded from the advertising council. I should like to close with the challenge that you make your voice heard in that council. **[The End]**

Consumers, Industry and Government

By GEORGE P. LARRICK

Commissioner Larrick of the Food and Drug Administration Presented This Paper Before the Fifty-fifth Annual Meeting of the Grocery Manufacturers of America, Inc. in New York City on November 12, 1963.

I AM GLAD TO APPEAR on the program of your fifty-fifth annual meeting at the invitation of your president and our long-time friend, Paul Willis. Mr. Willis has worked closely with us over a period of years. We have learned to respect both his judgment and his ability.

There is a growing public awareness of the interrelated interests and problems of consumers, industry and government in the food field. The consumer is manifesting interest in things he formerly paid no attention to or was little concerned about—witness the great stimulation of interest in pesticide residues on foods. This interest in many areas places the actions of both industry and government under a magnifying glass, so to speak. Both of our organizations are indeed subject to close scrutiny.

It is self-evident that there are broad areas of mutual interest among these three groups. The safety of our food is of concern to all, and the honesty of its marketing is likewise of common interest. So all of us start with a very great community of interest and common problems.

Let us consider three matters of concern to all of us: Communications, efforts to limit the occurrence of serious accidents, and the continuing need to develop closer relationships among all scientists with food problems.

In the matter of communications, we are all striving to improve the exchange of information between consumers and government and between industry and government. The consumer point of view is important both in law enactment and law administration.

Communication with Consumers

One of our most important sources of information on consumer points of view is our Consumer Consultant Program. First started

in 1953, it now involves one part-time representative in each of our 18 field district offices. One additional full-time representative will soon be placed in each office. Consumer views, comments and complaints transmitted to us through the consultants have proved very helpful. Mrs. Carla Williams, the director, described the program when she appeared, at Mr. Willis' invitation, before the Grocery Manufacturers of America's Consumer Service Panel last February. Our Consumer Consultant Program is helping us carry forward a goal recommended by the President's Consumer Advisory Council—the strengthening of the role of the consumer in the economy. It is noteworthy, however, that the Food and Drug Administration Consumer Consultant Program very much resembles the Consumer Information Programs of the firms and associations of the food industry, such as those of the Grocery Manufacturers of America, the National Canners Association, the Millers National Federation and the American Institute of Baking.

We welcome direct inquiries from consumers and reports on their experience with and reaction to foods, drugs and cosmetics. With increasing public awareness of FDA, our contacts with the public have so multiplied that we now have a Consumer Inquiries Section to handle such inquiries. It is part of our Consumer Education Branch which develops and disseminates educational publications for consumers.

Communication with Industry

Our program of communications with industry is of long standing. We have always had an "open door" policy. Any manufacturer or other interested person may seek our advice at any time by letter, by telephone, or by personal visit and he will be freely given our views on any problem or question of the application of the requirements of the Act. For example, our Division of Advisory Opinions alone has been receiving about a hundred phone and mail inquiries per day, plus numerous visits from industry representatives. Additionally, many technical and scientific questions are covered in almost continuous conferences between our scientists and those of industry.

Some time ago we established special branches in the Division of Public Information to deal with both consumer and industry needs. These branches have made it possible for us to increase the attention given to this phase of our work. One concrete result, already apparent, has been an increase in the output of publications and other informa-

tional materials designed to aid industry in understanding and complying with the Act.

Upon occasion special liaison groups have been established by industry to facilitate communications. For example, the Food Industry Liaison Committee in which your Association has a large role has been meeting with Food and Drug representatives to:

(1) Improve voluntary compliance with the laws by industry through more knowledge of the requirements;

(2) Provide information about food industry problems to the Food and Drug Administration and thus promote better informed administration of the pure food law; and

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

Our 18 field district offices maintain the same kind of "open door" policy as we in Washington and thus welcome opportunities to promote voluntary compliance.

Bureau of Education and Voluntary Compliance Created by Secretary Celebrezze

About three weeks ago, Secretary Celebrezze approved a reorganization of FDA which has been under study for some time. Among other things this establishes a new bureau, the Bureau of Education and Voluntary Compliance, which will help us give even more emphasis to these activities.

The Bureau will conduct a broad program of promoting voluntary compliance and cooperation between the public, the regulated industries, and the FDA through educational and informational activities. It will give increased attention to the consumer education function.

It is evident that past education and communication efforts have resulted in improved compliance, and a narrowing of areas where legal action is necessary. Obviously, when necessary, legal actions will be unhesitatingly and vigorously pursued but we do anticipate greater effectiveness in presentative enforcement under the new organization.

Your industry has been quite successful in limiting the occurrence of large-scale, serious accidents due to contaminated, commercially prepared food. You are indeed to be congratulated.

However, we must not relax as is shown by the recent instances in which botulinus poisonings have caused widespread public concern.

When such accidents occur, it is our obligation to take whatever steps are needed and to issue whatever public warnings are required to protect consumers. In doing this, we strive to make the warnings as clear and specific as possible. The producing industry can be of tremendous assistance, when emergencies arise, by taking immediate corrective measures. We think the steps taken by the National Fisheries Institute to deal with the problem of botulinus toxin in smoked fish is an outstanding example of prompt and effective action by a producing industry group. Promptly after our scientific advisory committee gave us its recommendations with regard to the botulinus hazard, the Institute adopted measures to safeguard health which were in accord with the scientific recommendations.

I need not tell this audience how quickly and efficiently the food distribution industries respond when there is need to protect the public health.

Our modern world is using science to a degree never before dreamed of. Science is to the modern world as art was to the ancients. It is the guiding spirit for all our actions. The gas chromatographic equipment of today can accurately analyze foods for pesticides, for example, down to a few parts per billion, and modern measurements of radioactivity in food reveal levels so low that scientists have had to devise a new system of nomenclature to discuss them.

Some of the test apparatus now employed by advanced laboratories, including our own, is costly. In recent years funds have become increasingly available to us and to other laboratories. But this is a relatively small part of the problem. Not only must funds be available, but all of us must have the trained, professional manpower to develop methods, to understand and employ those methods, and to interpret the results determined. How is this to be done?

Our scientific personnel are in constant communication with scientists all over the world. We participate in the activities of the World Health Organization, the Food and Agriculture Organization, and such groups as the International Union of Pure and Applied Chemistry in international affairs. We are familiar with the developing *Codex Alimentarius* designed to help develop world-wide standards of purity for food chemicals. In our own country, in helping develop modern food technology we must collaborate with universities, the Association of Official Agricultural Chemists, the National Research Council, the Nutrition Foundation, the American Society for Testing

Materials, the revision committees of United States Pharmacopeia and the National Formulary, the Institute of Food Technologists, the National Canners Association and state and federal agencies, among many others.

Our methodology must keep pace with scientific developments. Thus we are constantly engaged in scientific research for we must be as progressive technologically as you and the research institutions are, to fulfill our responsibilities to you and to the public at large. We help train state enforcement scientists, collaborate with the professional personnel of the food and drug industries, and where needed, help the industry to adopt the latest procedures. For example, we see increasingly the utilization of gas chromatographic equipment by the food industry in food control procedures before the marketing of a new food. Our laboratory scientists are always available for timely consultation as to the latest and best methodology available. We need (and have received) your cooperation in confirming their findings and in developing further improvements. All of us will benefit from full participation in the work of science.

Two New Scientific Bureaus To Be Established

To assist FDA in its participation we are establishing two new scientific bureaus in place of one. These are:

A Bureau of Scientific Standards and Evaluation which will consolidate the petition processing system and develop scientific compliance and performance data to be used in the determination of standards and tolerances; and

A Bureau of Scientific Research which will concentrate on the continuation and expansion of scientific research in methodology, testing analysis, and other areas.

Additionally we are forming a National Advisory Council to the Food and Drug Administration under the chairmanship of the Commissioner of Food and Drugs. This council will be comprised of citizens prominent in such fields as science, consumer activities, government, labor and law, who will advise the FDA on national needs and program and policy effectiveness.

Our foods remain high in quality and character primarily because of the very substantial efforts of the food industry as a whole. This, and your cooperation in bringing about improvements, have earned our highest respect. We look forward to continued, mutually beneficial cooperation as we work together to maintain the high quality of the American food supply. **[The End**

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

January Food Seizures Report.—Over 460 tons (921,568 pounds) of contaminated food were seized in 38 actions during December. Of this total, 362,790 pounds were in the "health protection" category involving four seizures of vegetables and hay containing nonpermitted or excessive pesticide chemical residues. Other food seizures were due to filth, spoilage, and unsanitary handling.

Charges of economic violations accounted for the seizure of 27,052 pounds.

Drug and Device Seizures.—Charges of misbranding with false and misleading therapeutic claims, inadequate directions for use, substandard or defective quality, subpotency, imitation of other drugs, repacking of physicians' samples, and shipment of drugs without new-drug approval resulted in 24 seizures of drugs and devices.

Cosmetic Seizures.—Two products, a nail strengthener and cosmetic lotion, were seized on charges of adulteration and misbranding.

Hazardous Substances.—Sixteen actions were taken because of failure to bear precautionary labeling required by the Federal Hazardous Substances Labeling Act. The products were a water repellent that has caused flash fires (11 actions) and a novelty glass toy containing ether vapor (5 actions).

Voluntary Actions by Industry.—More than 161 tons (323,208 pounds) of contaminated foods were removed from human consumption channels in 72 voluntary compliance actions during December.

A Washington grain storage corporation converted 180,000 pounds of barley into animal feed when it was found contaminated through careless use of rodenticide.

A Pennsylvania company destroyed 14,317 pounds of cocoa bean rejects and skimmings resulting from the reconditioning of moldy lots.

A Massachusetts cold storage warehouse destroyed 11,100 pounds of insect-infested dried kidney beans by dumping them into the local incinerator.

Drugs and Devices.—The drug industry voluntarily withdrew from the market nearly $163,000 worth of products no longer meeting necessary standards. Among those voluntarily ordered destroyed in the interest of consumer protection were $62,400 worth of drugs that had been exposed to excessive heat and water damage following a fire in an Oregon drug firm. An Indiana drug manufacturer voluntarily destroyed outdated stock of two products, and recalled a third when it was found that the suspension formulation was not satisfactory. The three products represented a potential retail value of $54,966.

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