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Food Drug Cosmetic Law JOURNAL

Papers Presented at the 1964 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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TO THE READER

1964 FDA-FLI Conference.—The concluding papers from the morning session of the Eighth Annual Joint Conference of the Food and Drug Administration and The Food Law Institute, Inc. are featured in this issue of the JOURNAL. The conference was held on November 30 in Washington, D. C.

The main topic, "Science Promotes Voluntary Compliance," was discussed in four papers. The first paper, considering the nonmedical aspects, was by *O. L. Kline,* FDA's Assistant Commissioner for Science Resources, and appeared at page 669 of the December JOURNAL, along with the first six papers delivered at the conference.

In an article beginning on page 5, *Dr. Joseph M. Pisani* looks at the topic from the medical viewpoint and points to the unique integration of efforts and growing cooperation among FDA, industry and academic scientists to bring safe and effective prescription drugs to the consumer.

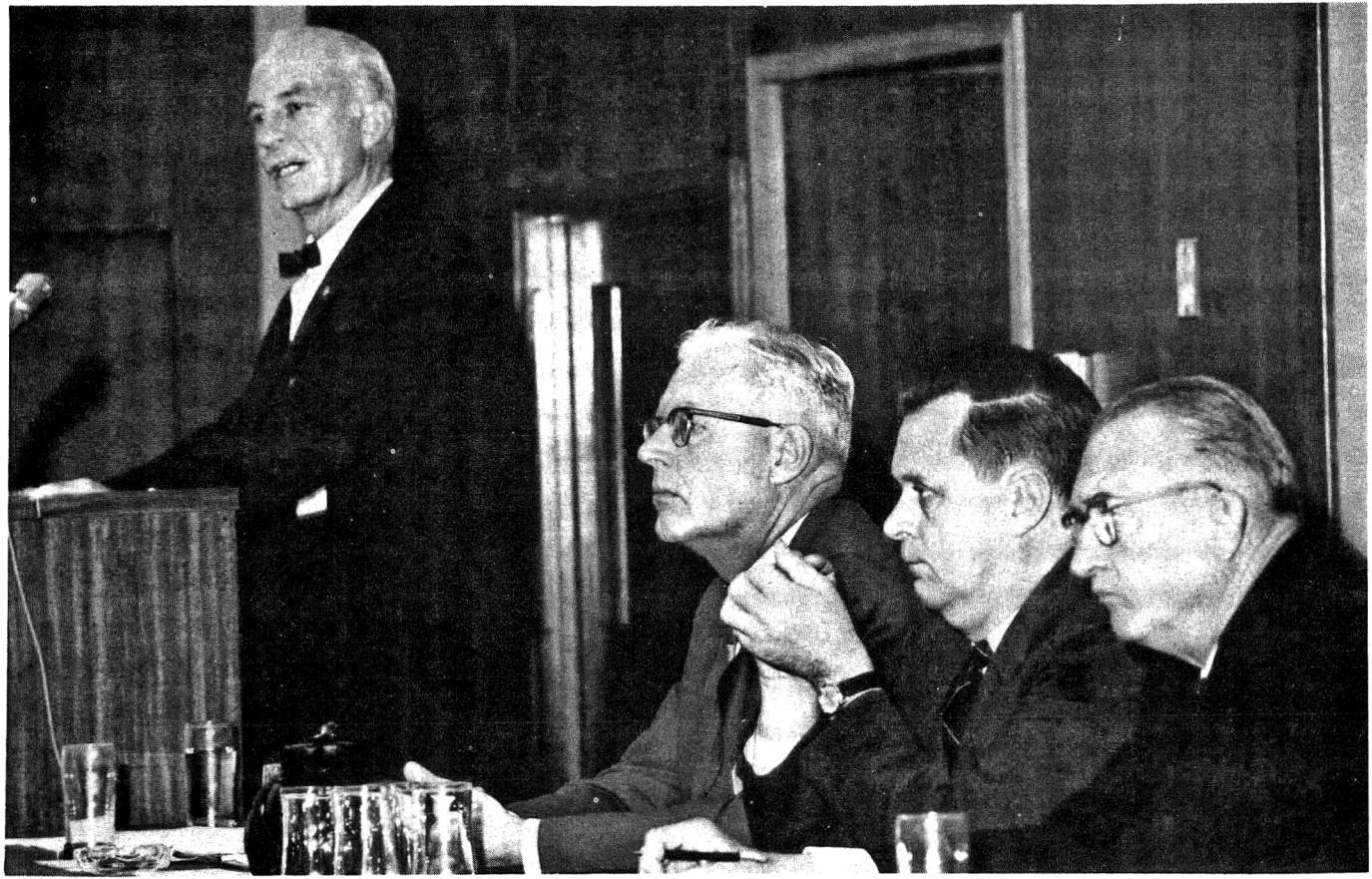
"[S]cience, because of its very fluid makeup, promotes voluntary compliance not only where laws are involved, but also where moral issues are concerned." This opinion is expressed by *Dr. Austin Smith,* president of the Pharmaceutical Manufacturers Association, who spoke for the drug industry. His remarks appear on page 11.

At least one-half billion dollars is spent annually on scientific research, development and controls in the fields of agriculture and food technology, estimates *Dr. Robert M. Schaffner,* vice president, research and quality standards, Libby, McNeill & Libby. In an article beginning on page 17, the food industry's spokesman, Dr. Schaffner, declares that much of this money is devoted to the area of voluntary compliance, to make sure that our food supply is the most nutritious and the safest that has ever been offered to any nation.

In an article at page 22, *William W. Goodrich,* Assistant General Counsel for Food and Drugs, Department of Health, Education and Welfare, states that drug regulations are a means of communicating to the regulated industries what is expected of them to comply with the law.

The luncheon address was presented by *W. Howard Chase,* chairman of Howard Chase Associates, Inc. The address appears on page 28.

The afternoon session of the conference was devoted to a series of five simultaneous panel workshops on the general topic of "What Industry Needs from FDA for Better Compliance." Three of the papers from the first workshop, "Sanitation and Quality Controls," are found in this issue, beginning on page 40. The authors are *Robert S. Roe,* FDA's Director of the Bureau of Scientific Standards and Evaluation; *Charles H. Brokaw,* manager of the Processing Quality Control Department of the Coca-Cola Co.; and *Karl F. Lang,* manager of Quality Control, H. J. Heinz Co.



Shelby T. Grey, Deputy Director of the Food and Drug Administration's Bureau of Education and Voluntary Compliance, Is Shown Addressing the 1964 Joint National Conference of the FDA-FLI. Franklin M. Depew, Dr. Edward M. Dempsey and George P. Larrick, Seated, Were Also Speakers at the Conference.

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Science Promotes Voluntary Compliance—The Medical Viewpoint

By JOSEPH M. PISANI, M.D.

Dr. Pisani Is Deputy Medical Director, Food and Drug Administration.

IT IS INDEED AN HONOR and an unexpected pleasure for me to take part in this Eighth Annual Conference of the Food and Drug Administration and The Food Law Institute. While I am sure my appearance is also unexpected from your standpoint, since Dr. Sadusk's name appears on the program, I wish I were just as sure my participation will give you as much pleasure as if he were here to address you. He asked me to convey his regrets for having to change his plans to be with you due to an unforeseen conflict in his schedule involving a mission overseas about which I will brief you a bit later on in my presentation.

The title of this section of the morning program is intriguing. "Science Promotes Voluntary Compliance" is at once both euphonious and harmonious. Webster's dictionary indicates that one interpretation of the word "science" is "the possession of knowledge as contrasted with ignorance or misunderstanding." Thus, in the interest of euphony, one might arrive at a subtitle such as "Comprehension Confirms Conformance." From the standpoint of harmony, one can regard the term "science" as being complementary to "compliance" since the former provides something that completes or makes perfect the latter.

In the writings of William Jevons, an English economist and logician of the 19th century, is found the concept that "a science teaches us to know and an art teaches us to do, e. g., astronomy is the foundation of navigation." From the standpoint of the drug manufacturer, this concept probably sums up rather neatly his analysis of the marketing of a new drug as being both a science and an art calling for a good deal of navigation.

In fact, by giving this concept and our semantic exercise an allegorical twist, I believe we will have arrived at our theme. This is, how can scientists in the FDA, in industry, and in the academic community best combine their talents to steer new drugs past the Scylla of new drug investigations, the Charybdis of new drug applications and the land of the Lotus Eaters, or new drug supplements, to safely and effectively reach their destination, the consumer?

The need for cooperative efforts by scientists is perhaps put in sharper focus by briefly reflecting upon the changes which have taken place in both our society and in pharmaceutical development since the turn of the century.

The population of our country has increased by nearly 60 million within the past three decades. There has been a pronounced shift from rural to urban living, for while the farm population was decreasing from 31 million in the late 1930s to 16 million today, the urban census has grown from 99 million to 172 million in the same period. Simultaneously, there has been about a doubling in the number of citizens 65 and older (from 8.4 million in the late 1920s to 17 million today). These population shifts have been coupled with increased personal consumption expenditures for foods, drugs and cosmetics. The increase in older consumers has created an increased demand for more special foods and more drugs—many of which are used for longer periods of time—than by the average adult population.

Pharmaceutical development proceeded at a slow pace until well after World War I. Prior to that time, the average doctor relied upon less than a dozen drugs which were relatively nonspecific, afforded symptomatic relief and were less likely to be harmful to his patients. Then came the new era in drug development. Laboratory experiments became more and more successfully applied to clinical medicine. Chemotherapy, which has its beginning with the discovery of "606," received further stimulation by the development of the sulfa drugs just before World War II and the development of penicillin during that war, and then really began to blossom during the past two

decades. The remarkable scientific advances and the speed with which drug development has grown to yield a host of new drugs in this time are vividly portrayed in the estimate which has been given that 90 per cent of the prescriptions filled today could not have been filled 15 years ago because the drugs had not yet been marketed. Further evidence of the growth of the drug industry is the sharp increase in consumer prescription expenditures from $150 million in 1940 to about $2.2 billion dollars today!

In view of these manifold developments to which we have briefly alluded, and others which time will not permit including, it is no wonder that Congress decided to promulgate new navigational charts in the form of the Kefauver-Harris Amendments of 1962 for new drugs to follow, from their port of embarkation as they are launched by their sponsor to their port of destination, namely, public usage.

New Amendments Influence Health Care

Have these new legislative amendments and their accompanying interpretive regulations as issued by the FDA really been harmful to clinical research on drugs and new drug development as some have claimed? Commissioner Larrick in a recent address to a NARD convention spoke on this point as follows:

> There is no question but that the Kefauver-Harris law is having a profound and constructive influence on total health care. It is interesting to note that this law has had the effect of inducing leaders in medical science to take a much closer look at their own procedures and at the relationship of the medical profession to the drug industry and to the FDA. From this has already come a great deal of practical good in the way of a better understanding of the scientific problems involved in developing new drugs and the need to accumulate full information regarding their effects, including adverse effects encountered by doctors in treating their patients.
>
> The integration of efforts by leading medical scientists and the growing cooperation of these scientists with the medical scientists in the FDA are important and helpful by-products of the new law. Over the years, these by-products may have as beneficial an effect on the public health as the direct requirements of the law itself.

Your speaker had the pleasure of taking part in a symposium recently at which a well-known medical scientist made similar and more specific observations on the same subject. He is head of the Department of Medicine at a medical school hospital teaching center in a large eastern city. He indicated he had observed a 15 per cent increase in the number of drug research projects with a 50 per cent increase of dollar support of such projects in his own Department of Medicine in the past three years. He further stated he felt research

workers were becoming familiar with the necessary forms and that it was an advantage to have a legal requirement for the establishment of research protocols and the submission of reports.

There are a number of activities already being carried on by the Bureau of Medicine or in the planning stage to foster cooperative efforts by scientists in government, industry and the academic community in the interest of the provision of new drugs which would be both safe and effective for public use.

FDA and Industry Cooperation

Industry scientists are no doubt well aware of the willingness of the professional staff of the Bureau of Medicine to confer with them regarding investigational drug studies and new drug applications within the limitations of the current backlog of work and staff to cope with the over-all workload. Likewise, the initiative for such exchanges of information will not infrequently come from the government scientist who is eager to know as much as possible about the new product from its scientific sponsors in industry. Such consultations and conferences are bound to increase as planned increases in staff and more adequate space and facilities become available during the coming year. In addition, there is a strong possibility of the development of research site visits, particularly where such visits would be helpful to all concerned in the assessment of new drugs which may present unique problems in evaluation.

There has been a growing liaison between the academic scientific community and the professional staff of the Bureau of Medicine. More and more our staff members are participating in scientific meetings throughout the country and submitting articles for publication which will be helpful in interpreting the government's responsibilities to the scientific community.

Increasing Use of Expert Advisory Committees

I am sure many assembled here are familiar with the increasing use of expert advisory committees drawn from the academic community such as the *Ad Hoc* Committee of Inquiry on the Possible Nephrotoxicity of Acetophenetidin (Phenacetin) Containing Preparations and, more recently, the *Ad Hoc* Committee on Aminopyrine and Dipyrone.

The investigational drug regulations raised a number of questions within the drug industry, the medical profession, and even within

FDA itself, as it began to prepare for implementing the new requirements. This led to the formation of the Advisory Committee on Investigational Drugs under the Chairmanship of Dr. Walter Modell. This group of outstanding scientists has recommended improved procedures and helped to answer a number of the more difficult questions about investigations of new drugs. An important outgrowth of their activities has been the development by the Bureau of Medicine in consultation with the Advisory Committee of the *Investigational Drug Circular*. This information piece has had three issues thus far during the past year and provides answers to the questions which are more commonly asked by drug sponsors and clinicians. Anyone who wishes to be put on the mailing list for these circulars should write to: Editorial Services Branch, Food and Drug Administration, Washington, D. C., 20204.

Also on the planning board are:

(1) The establishment of a Medical Advisory Board, as well as panels of experts who will be available for consultation on a regular and/or standby basis, and

(2) The recruitment of a small group of senior scientists with outstanding reputations in their respective fields to serve on a full-time basis. These well-known scientists would provide day-to-day support to the professional staff and their assistance would be invaluable because of their extensive background and experience.

Collecting and Disseminating Information on Drug Reactions

Another activity of the Bureau of Medicine which features scientific cooperation, and probably the last our time allocation will allow us to discuss, is our program for collecting and disseminating information about drug reactions. The true test of a drug's safety and effectiveness comes after it is marketed and used on 190 million people under all of the conditions which present themselves in medical practice. Hence, the first few years after a drug is marketed are really the beginning of phase IV of any given drug's clinical study. Adverse reactions not revealed in early testing sometimes become apparent; hence, we must continue to keep abreast of significant findings. We do this by:

(1) The collection of adverse reactions from the medical literature;

(2) The maintenance of an adverse reaction reporting program.

This consists of a surveillance procedure whereby designated hospitals and physicians routinely scan clinical facilities for drug reactions and submit monthly reports to us of this information. Since 1960 this program has grown to encompass about 100 civilian and 500 federal hospitals;

(3) The submission of reports of adverse reactions by holders of approved new drug applications and antibiotic permits as required by the 1962 laws;

(4) The exchange of information about drug reactions with the American Medical Association's Council on Drugs; and

(5) Receipt of information about drug reactions from a number of other sources, including the National Library of Medicine, state Departments of Health, and the National Institutes of Health.

Worldwide System for Exchange of Drug Reaction Information

In addition, FDA is working with the World Health Organization in attempting to develop a feasible worldwide system for exchanging information about drug reactions. WHO is currently holding a meeting in Geneva, Switzerland, on this very subject and Dr. Sadusk is attending this meeting. The United States will no doubt play a leading role in the development of such a system if it is at all possible.

In closing, as Dr. Frank Wiley, who is retiring at the end of the year, and was honored November 13 by the Pharmaceutical Manufacturers Association said:

> It is stimulating to note the freedom with which technical information flows between the scientists in regulatory agencies and the regulated pharmaceutical industries. It is quite common to find these men freely collaborating in the solution of a common problem. This does not mean that industry has gained domination of the agency impowered with its regulation, nor does it indicate that industry has relinquished control of the manufacture of pharmaceuticals to the Government. It does indicate that scientists, in organizations that were once thought to be in opposition, have decided that through cooperation and collaboration they can better reach the common goal, the production of better therapeutic aids for the benefit of mankind.
>
> A foreign visitor to the laboratory recently expressed some confusion when attending a conference in which personnel from regulatory agencies, representatives of pharmaceutical manufacturers, and members of the groups that develop standards for pharmaceuticals discussed freely their mutual problems and made plans for obtaining solutions of them. His amazement that such a conference was possible indicates that it is not a universal practice. After he had become convinced of the feasibility of such a conference, he observed that here might be one of the reasons for the leadership of the United States in the development and production of fine pharmaceuticals. **[The End]**

Science Promotes Voluntary Compliance in the Drug Industry

By AUSTIN SMITH, M.D.

Dr. Smith Is President of the Pharmaceutical Manufacturers Association.

ONE OF THE INTERESTING and encouraging facets of life in this country is the general feeling on the part of the public that guidance by the free enterprise system is preferable to domination by government. There are some who probably will dispute this statement but facts based on sound surveys prove the public desires private enterprise to government enterprise except where the latter is essential to fill existing voids. While this is commendable in view of the way our country was born and has grown, it at the same time offers a continuing challenge to make certain that the voids are as few and as shallow as possible.

In this respect the drug and other industries are not unique, particularly when they are related to health. Because health ranges from emotional to political, economic and security issues, any activity involving drugs, food, sanitation and health services is subject to headline treatment often far out of proportion to its importance. It is necessary, then, for those in these areas not only to be mindful of laws but to bend over backwards to comply with them. And it is equally essential for those who make laws or issue regulations to bend over backwards when health is concerned to assure fairness and reasonableness. Furthermore, when a law or regulation is unnecessary or harmful, it is equally important for the affected parties to advocate change. The Pharmaceutical Manufacturers Association has done this on occasion and will continue to support such a principle. To move either way, that is, to introduce a law or regulation, or to resist and demand redress, requires facts, the acknowledgment of which is of growing daily importance. Unfortunately, the place in which this belief is tested is more frequently the courtroom—at least so it seems for the drug industry—than where one might expect it, namely, in the halls of science.

Difficulties in the Courtroom

If medical science could be reduced to the application of equations and formulae and to the use of computers there probably would be fewer tests in the courts. Those who found themselves in this area of activity in our society probably would be there because of deliberate flouting of a law. Sometimes, though, there are people involved in court actions whose intents are free of thought of deliberate violations. This does not occur solely because of ignorance on the part of the defendants. Too often it rests on the inability of medical science to provide facts—sometimes even inability to provide scientifically defensible opinions—in areas of controversy.

This inability to demonstrate that two plus two equals four in any situation may puzzle some scientists, and many nonscientists, who are not familiar with the vagaries of the animal body, indeed of the individual cell. And it must be particularly frustrating for those who are asked to resolve important issues without enough data at hand to satisfy all curiosity and threats of criticism. But this is the world we live in. Sometimes we know the answers to scientific questions, sometimes we do not. In fact, we are indeed fortunate at times if we realize that we know we do not know. Too often there are some strong and influencing opinions expressed by those who not only do not know, but do not know they do not know.

Basis of Laws Relating to Science

A law, or ensuing regulation, is supposed to be based on the ability to demonstrate by fact some particular line of reasoning. Since science does not yet provide all the answers to the new questions being raised almost daily in our modern society, it is important for members of the health complex to be able to rely on at least the best informed opinion and the integrity of those who are guided by good conscience as well as good business sense. This applies to drug manufacturer, researcher, bedside practitioner, hospital administrator and other members of the health team. Science is moving faster than our laws and regulations but it is not yet sufficiently revealing to permit the adoption of laws and regulations that would preclude any possibility of error in judgment or in act.

Sometimes Congressional demands may cause pressure for legislative halls and the courts to move when they do not have sufficient facts. To keep such actions to a minimum, voluntary compliance with what seems scientifically sound and reasonable is obviously a way

to prevent or fill such a void. And science promotes voluntary compliance. It must, for to do otherwise would result in such restrictive legal control that the truth of medical progress yet to be unveiled would be hidden by barriers of ignorance.

Problems Inherent in Areas of Science

Let me be more specific in this respect by referring to the problems obviously inherent in some questions raised by scientific bodies. For example, the European Society for the Study of Drug Toxicity met recently and discussed factors influencing toxic reactions to drugs. One speaker mentioned a relationship between mortality due to drugs and the season of the year. Another reported that the toxicity of a drug given to an isolated animal is less than that encountered when the drug is administered to a group. Why huddling together should exert a lethal influence is not known. Other participants suggested that environmental conditions, for example, atmospheric humidity, barometric pressures, cloud conditions and wind may affect resistance to drugs. Still another stated that urinary pH can affect drug toxicity. Interestingly, one speaker who discussed the possibility of a government creating its own test agencies warned that if this were tried it might well hold up drugs unreasonably and waste time and effort to accumulating records of a "proliferation of ridiculous tests."

What this means in substance is that medical science is like a lady being wooed but whose hand is not yet won. She still remains independent and unpredictable and therefore not controllable by law or regulation. For her, voluntary compliance to meet her whims is the only way to be sufficiently flexible to cope with the unpredictable. There is not yet sufficient information to allow laws and regulations to govern all situations in which the application of scientific knowledge is important. For example, dependably revealing tests to determine if and how deformed children will be caused by drugs, chemicals, or even heredity are not yet available. This is only one of many but headline provoking examples. So if there ever was a time in our history for the need for sharing medical information and for providing a forum for medical differences of opinion, this is it. Congressional, regulatory, business, professional or public pressures cannot be allowed to supersede wise decisions when life and death are involved.

Thus it seems to me that science, because of its very fluid makeup, promotes voluntary compliance not only where laws are involved, but also where moral issues are concerned. Neither morality nor ethics

can be determined by legislation. Only facts—although theories sometimes are similarly treated—lend themselves to regulatory supervision.

Services of Scientific Agencies

The Food and Drug Administration and other governmental agencies with regulatory responsibilities have most challenging opportunities today to secure well qualified scientific talent, to seek sound scientific advice, and to work in an atmosphere of helpful interchange of information. So does industry, particularly those segments of industry identified with health products. And so do the health professions and others providing ancillary services. Certainly the drug firms of this country have an obligation and a willingness to find good scientists and scientific guidance. There have been times when gaps in this objective have opened up but, in general, these have been due to lack of necessary knowledge and guidance and not to questionable intent.

The drug industry has about 15,000 employees engaged in scientific activities but no one knows—at least I don't—how many others lend their services in consultative and exploratory research capacities. It is most encouraging to read about the FDA's upsurge in interest in doing a similar thing through consulting committees. This truly will help encourage compliance with any needed laws and regulations on a voluntary basis. And it is equally reassuring to learn of the increasing interest of scientific and professional organizations in not only the products of science but the ways in which the flow and the use of these products are regulated.

If I may be specific again for just a moment or two, I would like to mention projects by well known bodies that demonstrate, I believe, how science can promote voluntary compliance.

Pharmaceutical Manufacturers Association Activities

The Pharmaceutical Manufacturers Association some years ago adopted a series of suggestions for encouraging plant sanitation. More recently it issued a substantial report on plastics. It is working on color additives. It has studied automatic ampul inspection machines, drug induced blood dyscrasias, and steroid codes. It has done many other similar and similarly motivated things through its sections and committees. Perhaps the most recently publicized effort was its underwriting by an enabling-grant the work of the Commission on Drug Safety. It also underwrote by grant a conference on teratology, a

general meeting of scientists and scientific organizations, and two workshops on teratology to help train more people in this field of study.

Other activities of the PMA and its individual firm members could be cited one after another, but so could this be done on behalf of other bodies in academic, research, professional and governmental circles. For example, the newly created Drug Research Board of the National Research Council might be mentioned as evidence for the need to search for yet undiscovered facts. All of which causes one to ask how can presumably informed people say it is possible to adequately regulate safety and medical judgment in the framework of existing knowledge, especially when in some instances there is more lack of knowledge than availability of knowledge? The answer to this question is obvious on occasion, but it only emphasizes, it seems to me, the need for voluntary compliance not just with law and regulation but with good sense and good judgment.

Hopefully the FDA and the drug industry during the months and years ahead will not be faced with some of their recent problems and will be able to encourage cooperatively the furtherance of the concept of voluntary compliance particularly since science in today's world provides the essential ingredients for such an approach. If we can do this within the restrictive framework imposed by science, all will benefit, but the ones who will be helped most will be those who become ill.

Summary

As I think for a moment about the words in the preceding paragraphs of this comparatively brief address, I wonder if some may construe my statements to imply denial of the need for laws and regulations in the health field or a plea for more independence on the part of regulated health industries and professions. Neither was in my mind. What I have tried to emphasize is that science provides yardsticks for measurements, and without such yardsticks it is difficult to define and apply appropriate laws and regulations. Thus, before all needed facts are assembled, careful judgment and keen discernment by those possessing scientific facts are essential and are more important than those without facts, at least when sickness and death are involved. This is in its own way a form of voluntary compliance, at least voluntary compliance with the spirit that motivates self regulation. Then when the facts become available, appropriate laws and regulations for fair application to all can be considered and, if indicated, subsequently issued.

So, a form of voluntary compliance becomes applicable before there are enough facts for regulatory measures, and afterwards it becomes possible because there are revealing guidelines. Scientific knowledge, advice from scientists and the integrity of those who look to the future and not just to the immediate make possible voluntary compliance in all shades of its definition. And the sharing of this knowledge by all who have mutual interests encourages further the development of voluntary compliance whether it be done to reflect a desire to do what is right morally or to reflect an awareness of existing laws and regulations. But since science is not yet all revealing there must be ways by which differences of scientific opinion can be explored and the reasons for these differences made evident. Otherwise voluntary compliance and science will become at best only distantly associated acquaintances instead of the closely related partners now possible. [The End]

BUREAU OF MEDICINE REORGANIZATION ANNOUNCED

Reorganization of the Food and Drug Administration's Bureau of Medicine was announced January 10 by Commissioner George P. Larrick. The changes took place the following day when personnel of the Bureau moved to new offices in Arlington, Virginia.

The reorganized Bureau consists of the following divisions, branches and functions:

The Office of the Medical Director which will handle all administrative services, including personnel matters, records and communications;

The Division of New Drugs consisting of the Investigational Drug Branch, which evaluates plans submitted by drug sponsors for proposed clinical tests of new drugs, the Medical Evaluation Branch which evaluates safety and effectiveness data and proposed labeling, and the Manufacturing Controls Branch which evaluates adequacy of drug manufacturing methods, facilities and controls described in drug applications. The Division of New Drugs is no longer responsible for follow-up of new drugs after marketing. This responsibility is now in the Division of Medical Review;

The Division of Medical Review consisting of the Drug Surveillance Branch, the Medical Advertising Branch, the Case Review Branch and the Medical Device Branch;

The Division of Medical Information consisting of the Adverse Reactions Branch which is responsible for preliminary review and analysis, the Hazardous Substances Branch, the Medical Literature Branch, the Data Processing Branch, the Drug Indexing Branch, and the Statistical Evaluation Branch;

The Division of Veterinary Medicine; and

The Division of Antibiotic Drugs which controls medical aspects of investigational antibiotics, drug evaluation for certification, and surveillance.—FOOD DRUG COSMETIC LAW REPORTS ¶ 2425 and 40,161.

Science Promotes Voluntary Compliance in the Food Industry

By ROBERT M. SCHAFFNER

Dr. Schaffner Is Vice President, Research and Quality Standards, Libby, McNeill & Libby.

THE POSSESSION OF KNOWLEDGE as distinguished from ignorance and misunderstanding is one of my favorite definitions of science. Although one realizes, of course, that food science cannot be the sole criterion for drawing up, promulgating and enforcing various food regulations, it is encouraging to see the ever-increasing importance that is being placed on scientific results in the field that we are discussing.

I am sure that no one in business or government today is as ignorant or as misinformed as was a Midwestern legislator of about half a century ago who seriously proposed regulations which would have "simplified" calculations of circular areas by changing pi from 3.14159 to 3.

I believe that those of us in the professions of law and science must, however, continue to inform the public about food science so that the people at large will only be interested in legislation and regulations which will encourage the food industry to spend increasing amounts of money to develop and produce new convenient and nutritious foods.

In 1964 the American food industry is spending $125 million for research and development, and probably a like amount for scientific quality control. This, of course, does not include moneys being spent by the suppliers to the food industry in their development of new containers, ingredients and equipment for our industry.

The universities and the various governmental departments are also spending large sums of money on scientific research, development and controls in the fields of agriculture and food technology. If all

of these expenditures were summed up, I believe that, conservatively, at least one-half billion dollars are being spent annually for these scientific pursuits, and much of this money is devoted to the area of voluntary compliance, to make sure that our food supply is the most nutritious and the safest that has ever been offered to any nation.

Let us now look briefly at what has been done by food science and its application during the past few years, and see what types of problems remain to be solved by the combined efforts of the scientists in both industry and government.

Raw Products and Pesticides

It has been estimated that if our modern pesticides were not being used in agriculture, the production of all agricultural products would be reduced by 25 to 30 per cent, and this would probably completely wipe out our $6 billion export of foods. We see, therefore, that not only would our American people have to spend more of their income on foods, but we would be unable to assist the developed and developing countries in feeding their populations.

The American food industry and the Food and Drug Administration are caught in a dilemma. On one hand, we must assure the public that it is eating foods that are wholesome and insect-free, and on the other hand, these foods must not contain harmful pesticide residues. This problem, of course, has been realized by the industry for many years, and both the effectiveness of the pesticides and freedom from human toxicity were investigated by the chemical companies in the 1940s—considerably before the Miller pesticide act was passed.

For example, extensive studies were made on DDT about 20 years ago. These studies showed both the effectiveness and the safety of this pesticide. At the recent research conference in California on the use of agricultural chemicals from a public health standpoint, speaker after speaker mentioned the fact that the storage of DDT in humans is no higher now than it was in the 1950s and that if this pesticide has fallen from grace, it is not because of scientific facts. It was claimed that no adverse effects exist in man because of the low-level, long-time exposure to this chemical. It would therefore appear to a scientist that ways and means must be found to establish official tolerance levels for this pesticide for all foods.

American industry has done an outstanding job in controlling the safe use of pesticides. The National Canners Association's protective

screening program is an excellent example. Its program includes supplying information to canners on the approved pesticides for specific crops; canners in turn give growers detailed instructions. Both growers and canners maintain field-by-field records of the use of the chemicals, and finally, the canner systematically tests his raw product to make sure the residues are below the established tolerances. The success of this and similar programs has proven that the voluntary compliance method is both efficient and adequate.

Sanitation

Scientific investigations of improved equipment and procedures have provided bacterial conditions in our plants that in most instances are better than one would find in well-run home kitchens. Numerous segments of the food industry, through their individual companies and the scientific organizations connected with their trade associations, have carried out investigations on raw produce washing, handling and preparation that have made giant strides in the past 20 years. During the past two years, the National Canners Association's research laboratories have carried out scientific investigations to improve the washing of raw produce. These investigations were jointly sponsored by industry and government funds and the results are now being used by the industry. This has reduced water requirements and has helped to solve the ever-increasing need for conserving water resources. Also, these newer methods of washing result in products that are freer from all types of contamination. New studies are under way in which scientists will investigate methods of reducing atomic fall-out contamination, should it occur in the future.

The food industry, in connection with its support of the Food Protection Committee of the National Academy of Sciences, has also encouraged a study in the general field of food microbiology, and we feel certain that new scientific investigations which are being prompted by this project will lead to still further improved technology.

Many of the leading food associations in such fields as dairy products, candy, frozen foods, and canned foods have for many years carried out educational programs on improved sanitation practices. Throughout the United States both management and workers in the food industry are receiving continuing instructions and education on this important subject. I believe that the food regulatory people agree with industry that these programs are benefitting the public.

Processing

The food industry is constantly improving its processing methods so that the finished foods are more appealing in freshness, nutrition, color and flavor. Although the canning process was invented by the Frenchman, Nicholas Appert, over 150 years ago, processing requirements for canned foods were put on a more scientific basis by canners, working with the National Canners Association, toward the end of the first quarter of this century. Recommended processes for a wide range of products were summarized and first published back in 1930. This work has continued throughout the years, and the value of this program was pointed out by Commissioner Larrick in May 1963 when he stated:

> After the groundwork for the processing operations was established, some of the time of these laboratories was devoted to the improvement of the quality of the canned foods, and many of the products on the market today represent a testimonial to this accomplishment. Throughout all, however, it has been reassuring to know that the N. C. A. laboratory people have never sought or tolerated quality improvement at the risk of safety.

We believe that this important voluntary cooperative venture by the canning industry speaks well for the policy of self-regulation.

Ingredients and Additives

Many of the convenience foods that are now offered to the public would not have been possible if the research laboratories of the food industry and their suppliers had not worked together to develop new additives. Investigations—many costing hundreds of thousands of dollars—were made to make sure that these ingredients performed their intended functions and were safe from a public health standpoint. A review of scientific literature going back to the 1920s and 1930s shows that this type of investigation had been going on for years before the passage of the additive and color amendments to the Food and Drug Act. Since the passage of these amendments, the procedures for carrying out these studies have continued to become more standardized.

In the field of additives, a current example of excellent cooperation between the scientific branches of industry, universities and the government is the preparation and publication of the *Food Chemicals Codex*. This project was carried out by the Food Protection Committee and received its financial support through grants from the National Institutes of Health and contributions from food manufacturers, suppliers and trade associations. The expert committees developing the speci-

fications for the chemicals consisted of scientists from industry, government and the universities.

Sections of the *Food Chemicals Codex* have been published in loose leaf form, and the first bound edition will come out in 1966. This book will be of great value to all of us interested in food manufacturing, and will be a tribute to and an outstanding example of the principle of voluntary compliance.

Food Standards

There has been much controversy during the past few years regarding food standards of identity. Many people in industry have become disenchanted with food standards because the language does not permit improvements in technology and often is of a recipe nature, calling for only a limited number of optional ingredients. The older food standards were promulgated before the passage of the food additive-food color amendments, and at least one of the purposes of setting standards at that time was to ensure that only ingredients generally recognized as safe were used as optional materials. Now that the newer and more straightforward methods of clearing food additives are in effect, the industry, government and the public should not need this older protection. It appears to me that many of the existing food standards and the food standards of the future could be promulgated in such a way that they would be more flexible with respect to optional ingredients. This would avoid the setting of standards which would freeze technology, hamper research, and, more importantly, tend to limit the benefits of research to provide better foods. Perhaps if we in the industry and those in government take a fresh look at this whole matter from a scientific standpoint, ways can be devised of improving our methods of standards-writing to keep food manufacturing abreast of improved methods and ingredients developed by research.

Finally, I think that if we all give increasing emphasis to the influence of science on foods, both industry and government can educate and inform the people so that there will be no room for food faddists and fear peddlers to interfere with our joint efforts to provide the finest, most nutritious, and most modern foods to the nation.

[The End]

Regulations—An Aid to Voluntary Compliance

By WILLIAM W. GOODRICH

Mr. Goodrich Is Assistant General Counsel for Food and Drugs, Department of Health, Education and Welfare.

LAST SUMMER a very distinguished law professor, who had participated in the drafting and the legislative support of the Federal Food, Drug and Cosmetic Act between 1933 and 1938, visited us to examine the several new laws the Congress has enacted. His purpose was to develop a seminar course on the control of environmental health hazards. He was especially interested in the Pesticide Chemicals Amendment, the Food Additives Amendment and the Drug Amendments of 1962. He spent several weeks in Washington studying our materials. As he left, I got the distinct impression that he had been somewhat overwhelmed by the scope of the legislative and administrative events that had come to pass to deal with new problems, some of which had not yet developed in the 30s and others of which were not then adequately understood.

Some days later, he called to ask for several copies of the regulations we had placed in effect. And after he received them and was ready with his plans for his seminar, he wrote that he had been greatly impressed by "what a tremendously intricate mechanism the Act has become." He suggested as a future goal the possibility of consolidating some of the provisions governing administrative action.

Consolidation, as well as any other means of simplification of complex regulatory laws is, of course, an objective highly to be sought. Perhaps we will one day see a codification prepared in the interest of simplicity. But meanwhile, it is the purpose of all our regulations for the enforcement of these laws, as well as the regulations dealing with specific subjects, such as food additives and new drugs, to communicate simply and more effectively to the regulated industries what we think is expected of them.

We hope to communicate in these regulations in such specific terms as to avoid to the greatest extent possible misunderstandings and

inadvertent violations. This is how voluntary compliance is achieved by regulations. We recognize, of course, that many of the regulations are not models of clarity—but we would like to think that this is due to the nature of the problem, rather than ineptness in the art of communication.

Anyone looking at the current Part 21 of the Code of Federal Regulations cannot fail to be impressed with the magnitude of Food and Drug Administration operations. These regulations in the last annual revision covered more than 1,100 pages of printed material. Indeed, lawyers frequently call my office or the Division of Advisory Opinions in FDA with questions that are answered in detail in the regulations, but when they are referred to the Code, their first inclination is to turn to the yellow pages for an expert in this specialized field.

Many of the regulations have been in effect—unchanged—since 1939. Others are as new as today. All are concerned with situations and practices that do not remain static.

Certainly some of the old labeling regulations are in urgent need of revision. Some problems that have never been the subject of definitive regulations need to be dealt with. The dietary food regulations are obsolete by any standards whatever. The entire process of review and revision is a never-ending one.

Today's Regulation-Making Processes Compared to Those of the Past

How does the regulation-making process of today—and its results —compare with that which we knew a few years ago?

First, there is the requirement that all regulations expected to be binding on the public be published and codified in a central place. At least once each year the code is reviewed to eliminate obsolete material. The annual revision is soon to be published. In recognition of the rapid change that is occurring here, Title 21 appears in paperback form for ready use and prompt revision.

Second, the annual revision is followed up, no sooner than it is published, by changes printed in the daily issues of the *Federal Register.* So if one wishes to follow the regulatory process, it is essential that he learn to handle that publication.

Third, we no longer publish the informal advice we once offered as *Trade Correspondence.* Instead, following the requirements of the

Administrative Procedure Act, all statements of general policy and interpretation are formalized at least to the extent needed for publication in the *Federal Register*.

Finally, much of the grist for the regulatory mill that is published now does not originate with FDA, but arises from petitions and proposals offered by persons who must seek and obtain advance approval of proposed practices.

This brief summary may well make one yearn for the good old days—when rules were few and were included in mimeographed hand-outs, and the deadlines for comment and recommendations on notices of proposed rule-making were not yet with us.

But upon reflection, we feel sure that it can be agreed that the broadest and least expensive compliance is voluntary compliance by the great majority of persons who wish first to learn what is expected of them, and who have a ready means of participating in the development of any regulations which may affect them.

With this as our premise, let us look at just how the procedures we are using can be expected to serve the goal of voluntary compliance.

Procedures Followed in Proposing New Regulations

Typically, a proposal for a new regulation or for a change in an old one originates with some interested person or group, or upon the Commissioner's initiative. The proposal is published as a notice of proposed rule-making. Interested persons are invited to submit comments and suggestions for improvement or objections to the proposal at that stage. There is a deadline for action.

This notice is not hidden in the deep recesses of the *Federal Register*. We ordinarily issue press notices of any proposed rules which have a wide public or trade interest. These press notices explain what the action is all about, what is planned to be done, and when comments should be offered. FDA's Division of Consumer Education has developed *Memo's for Consumers* to explain proposed actions and to invite consumer reaction. Its consumer consultants are alert to proposed rule changes and are seeking consumer reaction to them. As a result, our hearing clerk now gets more mail than almost anyone in the Department. These comments offer a broad spectrum of opinion ordinarily, though sometimes we receive a deluge of mail with essentially the same comments. Inspired comment of this sort is not very helpful in improving the rules.

All comments filed with the hearing clerk are made available to the public for inspection, unless a specific request for confidential treatment is made. I hasten to add here that there are few such requests, though we do sometimes receive grieved complaints inquiring why particular letters have been made available to the trade or public press. The public file has the advantage of sharing with all who may be concerned the views and reasoning of others who are interested in or affected by the regulations.

The necessity for public comment has the merit of calling for responsible self-examination by the individual and industry spokesmen who write to us. At this very moment, for example, a notice of proposed rule-making is serving to bring under re-examination widely divergent practices in the promotion and sale of diluted fruit juice drinks and beverages. We can think of no better way to approach such an industry and consumer problem with the hope for a fair and proper solution.

Value of Informal Conferences Cited

While proposed regulations are in the comment stage, we have frequently found that informal conferences with individuals and organized groups serve to promote better understanding of our objectives and a better understanding on our part of some of the problems which may be involved.

An excellent example of this arose out of the publication of our proposed regulations on the distribution of new drugs for investigational use. These regulations, strongly supported by the public, were viewed with dismay by the drug industry and some parts of the scientific community. There was considerable urgency in bringing them into operation as a public health measure. We met with a large number of groups representing the scientific community and the drug industry. Plainly the meetings served to reassure the industry and the scientists that the over-all plan of the regulations was a sound one, and to convince us that revision was needed to achieve a needed flexibility that would assist in the sound development of new drugs.

These regulations, once roundly condemned as unnecessary bureaucratic meddling in scientific research, have come to be regarded as an important step in improving the quality of scientific research with new drugs. They could not have been developed in satisfactory form without the assistance we obtained through these informal conferences.

Action on the Proposed Rule

After all the comments are in, and informal consultation has been completed, the next step in the regulation-making process is to act on the proposed rule. This may or may not be followed or accompanied by a public hearing, depending on whether the Congress has provided for a hearing in the particular circumstances or whether the Commissioner feels that a public hearing would assist in the development of any additional facts that should bear upon the content of the regulations.

In the days when the original regulations were being developed, there was no organized method of soliciting public participation in the rule-making. There were hearings of a sort—if we can call large mass meetings in the Department of Agriculture's auditorium hearings. Experience has shown, we believe, that more thoughtful and better-organized comments can be expected in written analyses of proposed rules. This is the procedure that is generally followed.

But occasions do occur when there is a need for the further development of the facts which should underlie sound regulations. When this is so, a hearing is called for and is conducted in an orderly manner to develop a record for action. An example of this may be found in the development of the prescription drug advertising regulations. While a full-blown hearing was not necessary, it was possible to develop enough facts in a short time to enable FDA and the industry to achieve a meeting of the minds about what regulations were needed and about how the regulations would work. This was a case where a few pictures (or ads) said more than a thousand words could have told us. Voluntary compliance on a prompt and effective level resulted.

After regulations have been promulgated, there is the possibility of court review. For many of our regulations, court review by direct action is authorized by law. In others it is not; review of those regulations ordinarily awaits a regulatory action in which they are called into question in a specific factual setting. Recently, two district courts have held that regulations affecting industry practices may be reviewed in a suit for declaratory judgment. One of these cases is on appeal, and the other is in preparation for a trial of unique proportions.

Assuming that the procedure has been completed and judicial review has been exhausted, what is the effect of the regulation?

Most of them are final and have the same binding effect as a statute passed by the Congress. Others embody interpretations which we hope the courts will apply.

Constant Review of Regulations

But this does not mean that once the regulation is promulgated it achieves the status of an untouchable. If regulations are to serve the purpose for which they are promulgated—to aid in the efficient administration of the Act—they must withstand critical evaluation in their actual performance. And clearly if they contribute to a misunderstanding of the demands of the law, they must yield to correction.

Not only does the law itself encourage persons affected to propose amendment or repeal of any regulation that is deemed inappropriate, the FDA maintains a unit at the Assistant Commissioner level charged with the constant appraisal of regulations and regulation making. We welcome constructive criticism of any and all of our regulations, and we are prepared to respond to any needed improvements.

The tone has been set by the Commissioner himself who said earlier that we are exercising many means of publicizing our regulations to promote better understanding, and that we welcome all ideas which may lead to greater voluntary compliance in the public interest.

[The End]

HARVEY W. WILEY AWARD

Nominations for the ninth annual Association of Official Agricultural Chemists Harvey W. Wiley Award are now open, it was announced by Mrs. Margarethe Oakley, President of the Association. Nominees need not be members of the AOAC to be considered for the $750 award.

The Wiley Award was established in 1956 by the Association to recognize an outstanding scientist or scientific team for contributions and achievements in analytical methodology of interest to agricultural and public health scientists. Subject areas include foods, drugs, cosmetics, feeds, fertilizers, pesticides, vitamins and other nutrients, and general analytical chemistry. Methods of analysis for these and other commodities are studied by the AOAC, and those which are approved are published in its laboratory manual, "Official Methods of Analysis," which is used by research and regulatory scientists throughout the world.

Nominations should be detailed and include a biographical sketch, outstanding scientific and professional accomplishments, and a list of scientific publications. Eight copies of each nomination for this year's award should be received by Luther G. Ensminger, Association of Official Agricultural Chemists, Box 540, Benjamin Franklin Station, Washington, D. C. 20044, before April 1, 1965.

The Near and Far Horizons of Total Health

By W. HOWARD CHASE

Mr. Chase Is Chairman of Howard Chase Associates, Inc.

I HAVE NEVER BEEN SURROUNDED by so many people—each of whom knows much more about this field than I. It *is* a humbling thought. In one sense my mission is to represent Everyman (with a capital E)—that vast anonymous group whose hopes, fears intentions and votes *can* and *do* and *will* change the environments in which all of us do our work.

In a nation in which wide differences of opinion are the rule, no the exception, almost everyone will agree amiably that the "publi interest" or the "general welfare" (as the Constitution calls it) is th first concern of our national life, and of prime importance to the food drug and cosmetic industry.

Fortunately, this consensus exists. For if all roads lead to thi particular Rome, some take the high way, and others take the low. In any event, there are infinite paths to the attainment of "the publi interest" and considerable differences over which routes most nearly achieve the objective.

This Eighth Annual Conference of the Food and Drug Adminis tration and the Food Law Institute is, in a sense, an in-gathering o road builders and map makers. Certain demonstrably efficient high ways toward public health will be improved. Some sharp curves wil have to be straightened and perhaps some new danger signals installed These activities fall into the road-building or maintenance department

My own exposure—in more depth than I had anticipated—indi cates, however, that we who represent both industry and governmen are today more map makers than maintenance men. Map makers hav as much concern for the far horizons as for the immediate milestone

Consumer Protection Is Goal

Our objective, the protection of the American consumer, which was also the goal of Dr. Wylie and the 1906 Food and Drug Act and which has yet to be fully achieved, is now only half-way house in the national scheme of things, measured against our responsibilities to the future and the new tools which await only our using.

Eyes have been lifted and frontiers explored. Physical and technological skills, electronic data processing and the mastery of matter and energy have given man tools wherewith to meet the requirements of man. This eighth annual conference which could preoccupy itself with yesterday's problems—and they haven't gone away—can be the opening salvo of a new phase of an ancient dream.

I refer to the concept of total health, in the physical, mental and environmental meanings of the term. I refer to the need for industry participation on a larger scale than any yet achieved in a partnership with the health sciences and the government to eliminate disease and the environmental causes of disease and ill health.

The drive today is larger than protection from contaminants, from filth and from chicanery. I propose that we are on the verge of a vastly exciting new frontier. Today's Holy Grail that challenges the venturesome and brave is the total conquest of pollutants and dangers in food, drugs, air and water. Even visual pollution is under attack. The time has come for careful review of the impact of the food packaging industry on solid waste disposal. The proliferation of packaged foods brings with it increased need for improvements in solid waste handling and disposal, especially in large metropolitan areas. The question can appropriately be asked: What responsibility, if any, does this industry have in helping find solutions to the waste disposal problem? Unless industry becomes the shield of the consumer-citizen—the champion of these great goals—industry will become the victim or pawn of social change, not its architect.

Trend Toward Principle of Interdiction

We have passed far beyond the age of *caveat emptor.* This is a fact of life in America. We are in the latter phases of consumer protection made possible by application of the legal principle of abuse. We now enter the age of interdiction, the principle of law by which the body politic guides its powerful drive into what President Johnson calls the "Great Society," and which—for the purposes of this audience—

I have called the national drive towards total health. We shall return to the laws of abuse and interdiction.

Now this is a far cry from the modest request of your president that I speak of "The Educational Problems of Industry," on "successful in-plant programs to promote plant sanitation and to promote adequate controls."

There should be an axiom, if there isn't, to "beware the half-educated man," at least if he seeks information. It was my good fortune to seek it, and to find it. My condition resembles that of the small boy who was asked to read and report on a book about penguins. His report was as follows: "The book told me more about penguins than I really wanted to know." Commissioner George P. Larrick, Surgeon-General Luther Terry, his predecessor Dr. Scheele, your President Franklin Depew, their principal aides, many industry advisors, and not least, my own colleagues have contributed to a vast array of knowledge that has freely and generously been made available to me. If meagerness of comprehension or miserliness of vision is evident here, the responsibility is my own.

The Impact of the 1906 Act

Let us first examine the maintenance of the old highway towards health protection pioneered by Dr. Wylie in the original Food and Drug Act. It made possible the application of the industrial revolution to the food and drug business. The great tradition of industry-government cooperation in this field had its beginnings when the Western Packers Canned Goods Association and the Atlantic State Packers Association gave Dr. Wylie a respectful hearing and endorsed pure food and drug legislation.

In the 40th anniversary celebration of the Act, arranged by the late Charles Wesley Dunn, my beloved boss, Clare Francis, spoke eloquently and frankly:

> [T]he Act [of 1906] gave honest manufacturers protection they needed from unfair competition at the very time when a great new opportunity—and a great obligation—opened before them. The national economy, gaining momentum with every year since the industrial revolution, was rounding the corner to the machine age and a new period of plenty and standard of living such as the world had never seen. In this process, food manufacturing [and the pharmaceutical industry] had a vital part to play. It has done so, . . . and the most impressive single factor was this: *The conditions created by the passage of the Act invited responsible businessmen to put real money into the food business.*[1]

[1] "Its Basic Value to Food Industry," 1 FOOD DRUG COSMETIC LAW QUARTERLY 379, 382 (September 1946).

Eighteen years later, Mr. Francis, perennially the protagonist of the public interest, can take pride in America's food industry—an $80 billion giant, the largest employer of labor, the largest user of transport, the most stable of all the industries, the source of the nation's foodstuffs, and the prime contribution to human energy and health.

But with industry growth and population growth, came Act enforcement problems. As Commissioner Larrick said to me:

> Most people in the 100,000 firms the FDA has dealt with are as honest, ethical, and devoted to public interest as anyone in Government. As we pursue our separate ways, our objectives are identical. We each want self-respect; we want the approval of others; we want to serve honestly.
>
> The manufacturers of food want to make pure, good, saleable food. This is precisely what FDA wants them to do. The industry leaders who meet at GMA or PMA see each other as decent, honorable people. They see the reputable companies which try to serve the public interest without need for regulation.

But FDA, continued Commissioner Larrick, sees also the fringe elements, the crooks, the fast buck artists.

> When misunderstandings between reputable companies and FDA arise—and they do—it is because FDA is an enforcement agency and because FDA and the honest manufacturer are looking at different ends of the public health spectrum.

Enforcement Problems Described by Commissioner Larrick

Perhaps we should devote a moment to the range and breadth of FDA's enforcement responsibilities as they exist today. In his 1964 report to Congress covering 1963, Commissioner Larrick described an array of problems mostly foreign to the reputable manufacturer, but they are real enough to the American people and to the Gideon's band of FDA enforcement officers.

(1) In 1963, there were 88,500 interstate establishments that produce, package, distribute, or store foods.

(2) There are 2,200 chemicals used by 73,000 food establishments. These include color agents, preservatives, emulsifiers, etc. Commissioner Larrick told the Congress: "They are essential to production of our modern convenient foods."

(3) There are 500 chemicals in 55,000 registered pesticide formulas. There are 375 chemicals and 40,000 formulations for food crop fertilization.

(4) 600 million pounds of pesticides were used by 5 million farmers in 1963.

(5) In 1963, 2½ million interstate shipments of raw fruits and vegetables were treated by chemicals during their growth cycles.

(6) It remains FDA's duty to protect the consumer from unsanitary and harmful foods. In 1963, 79 million pounds of food were seized for reasons of filth and 3 million pounds were seized in 68 actions because of direct health menace.

(7) Ninety per cent of all illegal drug sales referred by FDA to the Department of Justice involved stimulants (amphetamines) and depressants (barbituates).

(8) FDA estimates public expenditure of $500 million in 1963 on worthless drugs or devices.

(9) Add to all these the responsibility of policing 360,000 separate imported shipments of food into the United States.

FDA's Vast Responsibilities

One of the educational problems of industry is to understand and support the FDA in its vast responsibilities, even though the kind and type of company that supports the Food Law Institute is unlikely to have much direct experience with the enforcement functions of the agency.

In Commissioner Larrick's words to me:

> When FDA evaluates these problems, and proposes new law or regulations to meet them, the business and business association leaders see new threats to individualism, to progress, to new products, and to private enterprise itself. At the least, they see red tape, but FDA sees crooks.

If you were to probe deeply into Commissioner Larrick's operating philosophy, as I tried to do, you would find a quiet pragmatist, dedicated to the law, to the public interest, and to the proposition that a system of entrepreneurial enterprise can and does do a fantastic job within the law in meeting and satisfying public needs.

But as a pragmatist in a democratic society, Dr. Larrick and his associates are aware of the occasional conflict between science and social judgments. As he stated in his 1964 report to Congress:

> The judgments of society are not necessarily consistent with scientific facts. They are not always logical. They can be and sometimes are arbitrary. Even so, neither the Executive nor Legislative branches of Government can long ignore them. If it should become the overwhelming public view that society should drastically limit the risk, no matter how much good a drug can do,

then we would be forced to remove from the market many drugs whose good outweighs their harm. Such developments could seriously impede the progress of medicine.

Applying this also to foods, may I add that food technology could be comparably damaged.

It would be hard to find a single more trenchant, significant paragraph in its implications to the food and drug industries, anywhere in writing. Implicit here is the most urgent plea for responsible industries to engage their energies and resources into great public educational campaigns in tandem with government and in tandem with schools and universities, that truth may be served and that emotional shibboleths and prejudices not be allowed to obscure the fruits of science and technology.

Lippmann refers to "the tyranny of the temporary majority." Dr. Larrick says that "if it should become the overwhelming public view," right or wrong, in a democratic society the President, the legislature and the enforcement agencies must respond with action.

Certainly one may disagree with FDA actions taken under this philosophy. There is much to be said for conviction based on proved scientific truth, despite emotional pressures. I am sure others have said this to Dr. Larrick. There may be, and is, wide disagreement in medical circles, for example, on FDA's action in retaining opinion polling organizations to discover whether people misunderstand or misinterpret a word or words, and then prohibiting the use of those words on labels or products even when they are used in complete scientific accuracy.

Similarly, scientists can point to valuable end uses for certain drugs which have been disallowed altogether in the United States because of the violence of mass opinion.

However, these are isolated examples to prove the deeper significance of Dr. Larrick's comment. He is telling industry that its total participation in the process of public education is its sole and only guarantee of an informed opinion. He is also saying that uninformed and hyperemotional mass opinion, in a democratic society, can make a mockery of scientific fact and of men dedicated to truth. The thin veneer between the rule of reason and the witch doctor is education, and education alone.

I have brought you along this highway, not as preface, but to reaffirm with you the importance from the industry and government point of view of protecting the citizen from abuse. This was a revolu-

tionary concept in this country in 1906. It is an accepted public and industrial policy today, but it is only a fragment of tomorrow's goal—positive total health. Let us examine this goal.

The World Health Organization defines health as "a state of complete physical, mental and social well-being." Dr. Alanson W. Willcox, general counsel of the Health, Education and Welfare Department, describes health as "synonymous with human existence at its best." Writing on the role of law in public health, Mr. Willcox concludes:

> Our concern for public health, pitted as it must be against the unplanned consequences of free enterprise is a technologically explosive world, calls for a continuous play of imagination unbounded by the dogmas or even by the hypotheses of any one profession.

Before we can measure the impact of these modern winds of change upon even the two industries of food and drugs, it will be worthwhile to examine the past, not for itself, but to chart the development of law from the principle of *caveat emptor* to the law of abuse, to the law of interdiction—words you have heard me use but which have relevancy to the thesis of these remarks.

Ancient Customs

There is a clay tablet about 3,500 years old in the Istanbul Museum of Ancient Civilizations. In cuneiform characters these words appear:

> If a man is pure and someone gives him rotten bread, or tainted fat to eat, or gives him bread on which a spell has been cast, or fat on which a spell has been cast . . . then I will make him a particular offering.

Rome had its Libripens—the master of the public weights. In Alemanic countries the custom of consumer protection was coded into 12th century law. In 1120 AD, the penalty in Soest for adulteration of wine was death. In Dortmund in 1258, there was a law prohibiting a purchaser from handling meat before buying it.

Between 1444 and 1458 several tradesmen of Nuremburg were burned or buried alive with their adulterated products—a penalty which has not yet been proposed to our Congress.

One particular ingenious punishment seemed to fit the crime: tradesmen jeopardizing health by adulteration of their wares were imprisoned and given only their own products to eat.

Dr. H. Frenzel, president of *Codes Alimentarius Austraeus* Commission, spoke at length on these subjects before a conference on

harmonization of the food laws at the University of Brussels on October 15, 1964.

Principles of Abuse and Interdiction Discussed

He pointed out that, apart from the law of *caveat emptor,* there are only two methods of establishing a legal system concerning products for human consumption:

(1) The principle of abuse, and

(2) The principle of interdiction.

Under the principle of abuse (or abuse of privilege), everything is authorized which is not expressly prohibited.

Under the principle of interdiction, everything is forbidden which is not expressly permitted.

The food and drug industry is at this moment moving—or being moved—out of a principle of law based on abuse to the law of interdiction. One might say that the two industries are fuming more and enjoying it less.

Mr. Depew recognized this trend in April of 1963, in his speech, "The Philosophy of Enforcement of the Federal Food, Drug and Cosmetic Act."

> The factors of consumer protection were found to be of such over-riding importance as to warrant the imposition of . . . restrictions on the freedom of action of the industries involved.
>
> [T]here is a trend away from the philosophy of a regulatory statute which . . . separates judicial and legislative powers. . . .[2]

European Laws Follow Trend

Yet this transition is by no means limited to this country. Dr. Heinrich Steiger of the European Economic Community Commission declares that Common Market harmonizing legislation follows the principle of interdiction on all additives, coloring products and preservatives.

Professor E. J. Bigwood, head of Biological Chemistry and Nutrition of the University of Brussels, and Conseil Superieur de l'Hygiène of the Ministry of Public Health, points out that the Belgian Food Law of April 4, 1890, which permitted so-called "foreign matter" to be added to food as long as such matter was not explicitly forbidden

[2] 18 FOOD DRUG COSMETIC LAW JOURNAL 185, 189 (April 1963).

and not used to falsify or deceive has been totally replaced by the Act of June 20, 1964. Today Professor Bigwood continues, it is "forbidden to put on the market any foodstuff containing additives not previously authorized by the Minister of Public Health."

French law proclaims its "positive lists" of approved additives and expounds further in the antibiotic field that what is useful in fighting infectious disease may be harmful in promoting animal or fowl growth and must therefore be regulated.

Professor A. D'Ambrosia of Milan, a leading European scholar in food technology, proposes a food law for Europe based on interdiction policy—and this may surprise you—as practiced in the United States. He writes:

> Once an additive has been accepted in the U. S. A., following very strict tests performed by the Pharmacological Department of FDA, there should not exist any valuable opposition against its use in all European countries.

I do not propose to catalog *all* the food laws of Europe. Our purpose is to explore fruitful relationships between government, industry and the health sciences in the drive for total health.

American industrial leaders, who still like to feel innocent before being declared guilty and who equate interdiction with being adjudged to be guilty before being brought to trial, may be interested in the response of a French food industry leader, Georges Jumel, Secretary General of the French Confederation of Food Preserves Industry. Accepting the interdiction principle, he told the Brussels Conference that food and drug laws must combine three preoccupations:

(1) The public health;

(2) Loyalty—fair dealing to protect the producer, consumer, and tradesman; and

(3) Progress—the law must always be open to constant and sometimes revolutionary progress of science and technology.

Mr. Jumel does not find interdiction crippling to enterprise, provided that the regulating agencies are open-minded. I do not believe that either FDA or the Public Health Service will oppose Mr. Jumel's doctrine.

Returning to my thesis that all of us—industry, government, the health sciences and above all, the people—are embarked now upon a drive toward total health. I am trying to say, in my layman's manner, that the principle of abuse is no longer adequate to the concept of total health, and that interdiction has the backing of powerful social

forces throughout the world and seems likely to become the custom and the law of this land. Interdiction need not be government controlled. As Dr. Hall pointed out,[3] self-regulation can have the effect of law.

It is my secondary thesis that the governments of the United States and of Western Europe, in expressing the aspirations of the governed, have long since crossed the Rubicon and that it is now and in the future the responsibility of industry to recognize and live with the principle of interdiction—whether externally or self-imposed—to the degree that it contributes to the public good and industry's reputation. *I repeat, interdiction can be voluntary.*

Those industries which seize this nettle of self-regulation, which regard it as a classic opportunity in sound public relationships, can integrate themselves permanently as business institutions into the daily lives of the people they serve.

Speaking from the consumers' viewpoint on the food laws in Europe, Frau I. Landgrebe-Wolff, Director of Deutsche Gesellschaft fur Ernahrung, expresses herself in a manner which I think would be shared by Mrs. Esther Peterson in America:

> Food laws concern goods which serve to maintain life and which are at the same time subject to the instability of all life. To remain timely, these regulations require cooperation on an equal footing between producers, the processing industries, tradesmen, and consumers.

Once again, we hear this phenomenal accent on education and on cooperation between the power structures of our society. The co-directors of the Agriculture Directorate of the EEC, in reporting on progress thus far in harmonization of food laws, conclude:

> The legal standards cannot be enforced effectively unless methodical education of the concerned people be achieved.

The Surgeon-General of the United States, Dr. Luther Terry, suggests:

> We need problem-solvers in a much larger universe of problems than we have hitherto accepted as our responsibility. We must be masters of a body of knowledge in relationships and resources.

Industry Understanding, Leadership and Support Needed

Everywhere in my research on government I have found a yearning for industry understanding, leadership and support in the drive for total health. At responsible policy levels in business management,

[3] Richard L. Hall, "Self-Regulation in the Food Industry," 19 FOOD DRUG COSMETIC LAW JOURNAL 653 (December 1964).

I have found comprehension and intellectual dedication to the same drive towards total health that motivates the thoughtful public servant and the leaders of the health sciences.

The fact is that the business statesmen identify themselves and their institutions with the dominant aspirations of their customers and act pragmatically to help achieve them. They know that a system of production for profit can survive only so long as their customers and their country equate their profit with public service.

Proposals Offered

I propose that the men of good will in all government regulatory agencies related to health and the manufacturers of all consumer goods related to health create a permanent center for continuing education on their mutual responsibilities to total health.

I propose that The Food Law Institute be charged with organizing and financing such a center under Presidential Charter, with contributions from both the public and the private purse. I respectfully suggest that one cent per share per year of the food, drug and cosmetic industries may not be out of line as a preliminary approach to industry's share of the cost.

I propose that the National Advisory Food and Drug Council, appointed by Secretary Celebrezze on November 11, 1964, consider the foregoing propositions and lend its assistance to this staggering, but possible and necessary, educational task.

I propose that the Grocery Manufacturers of America, the Pharmaceutical Manufacturers' Association and the Manufacturing Chemists Association recognize their mutuality and join their resources to provide inspiring leadership from private industry.

Unlimited Opportunities

This latter part of the 1960s presents an environment of limitless opportunity to combine technology, profit and service—to combine the resources of industry, government and the health sciences in a vast drive towards total health.

Mr. Francis in 1946 said,

> All honor . . . to this law which made it possible for the honest and substantial manufacturer to throw his capital, his guaranty, his resources, and his researches back of a constantly expanding system of food production and distribution; which in turn gave the consumer a constantly wider variety of constantly better foods at a constantly lower cost . . . .[4]

[4] Work cited at footnote 1, at p. 385.

Is it too remote, too idealistic, to look to 1975 to hear a great industry leader of that date say something like this? "As the food laws of 1906 made possible the industrial revolution of the food and drug industries, as the Acts of 1938 and subsequent regulations, and the cooperation of industry and government made enforcement possible and practical in the consumers' interest, so did the FDA-FLI meeting of 1964 set new horizons—new dimensions for industry, the health sciences, and for FDA and PHS. For the first time in history, the major power centers in a national society are determined to throw their full weight into the drive to eliminate all environmental causative factors of disease, the pollutants of the food we eat, the water we drink, the air we breathe."

And then our mythical "Mr. Francis" of the future might conclude (or it wouldn't surprise me if he said it himself): "The spirit and energy demonstrated by industry, government, and health science leaders—working toward total health—captured the imagination of the American citizens, dissolved the residue of mutual distrust or suspicion that once existed between industry and government, in the food and drug regulation field, and demonstrated to all hostile ideologies that men of good will, using the tools available to them, could and did conquer hunger, malnutrition and disease."

I remind you, if I sound like a latter-day Pollyanna, that this is a mythical quote from a man who has always combined idealism with a most practical set of operating concepts. One of the great poets has written that "Man's reach must exceed his grasp." I remind you that men and institutions are not evaluated and adjudged solely by the fruits of their labors, but by the high purposes of their goals. The great religions are founded on simple beliefs in the great goals of mankind. Dogma *follows* faith, it does not lead it.

In a little known passage, Lincoln said,

> The dogmas of the quiet past are inadequate to the stormy present. The occasion is piled high with difficulty, and we must rise with the occasion. As our case is new, so we must think anew and act anew. We must disenthrall ourselves.

Conclusion

On that note I conclude. Let us disenthrall ourselves from all earlier notions of the limits of our responsibility to our fellow man and become his champion in the drive towards total health. I promise you that Everyman will welcome and reward his champions. **[The End]**

Sanitation and Quality Controls

Comments by ROBERT S. ROE, Moderator

"Sanitation and Quality Controls" Was the Subject of the First of the Afternoon Panel Workshops on the General Topic of "What Industry Needs from FDA for Better Compliance." Mr. Roe Is Director of the Bureau of Scientific Standards and Evaluation, Food and Drug Administration.

DURING THE PAST YEAR the *Journal of the Institute of Food Technologists,* in recognition of the 25th anniversary of that organization, has published a number of review articles on various aspects of food technology. For instance, in the July 1964 issue, an article by Bruce H. Morgan entitled "A Quarter Past One" reviews a quarter of a century of progress in agriculture and in food processing. The article contains discussions under such headings as "Pacing Plant Sanitation," "Microbiology Moves Forward," "The Case of Additives," "The Explosion in Technical Advances," "Radiation Uses," and "Technology Affects Packaging." Emphasis was directed in this and other articles to scientific advances and new technological applications in food processing.

The September 1964 issue of the *Journal* presents a series of articles on the general subject "Perspectives and Projections in Food Technology." Here, too, are several articles pertinent to our subject today. As a matter of fact, one of our panelists is the co-author of an article on "Quality Control in Processing Foods." Another article in this issue is entitled "Progress in Food Plant Sanitation." Subjects discussed in these articles include preventive control of insects and rodents, sanitary design of buildings and equipment, microbial quality, problems of waste disposal, specifications and test procedures, and statistical quality control.

Certain principles of sanitation, manufacturing and packaging controls have been well established and are generally known throughout industry. New problems present themselves with changing technology and with the advent of new products and new procedures. Hence, our subject today "Sanitation and Quality Control" as regards

food production within the context "What Industry Needs from FDA for Better Compliance" is certainly timely and we anticipate lively and worthwhile discussion.

A quotation from Santayana which appears in one of the *Journals* to which I have referred seems most applicable. The quotation is "Those who cannot remember the past are condemned to repeat it." Let us hope that in remembering the errors and mistakes of the past we can avoid repeating them as we apply our past learning to our current problems.

Our discussion will be started with brief presentations from the four panelists. The two representatives of the Food and Drug Administration will outline (1) what has been done by FDA in attempting to provide helpful information to industry, and (2) the information available to industry from field investigations and inspections conducted by FDA.

The two representatives of industry will outline their views as to (1) what industry needs, and (2) areas of possible improvement or innovation in the relationship of industry and FDA, perhaps citing examples for illustration. **[The End]**

Comments by CHARLES H. BROKAW, Panelist

Mr. Brokaw Is Manager of the Processing Quality Control Department of the Coca-Cola Company.

SINCE MY INTRODUCTION to this Conference rather clearly emphasizes my Florida background, I think it is only logical for me to consider our topic primarily from that context. While in the citrus industry in Florida I was, quite frankly, unaware of any substantial problems of sanitation of an essentially regulatory nature. To be sure, process sanitation was a constant problem from a quality control viewpoint, but the industry was cognizant of it and exhibited, in my opinion, very advanced sanitation concepts. Of course, the Florida industry is highly regulated by state agencies who do an excellent job of assisting packers in maintaining sanitary standards. At any rate, my few personal experiences with FDA sanitation inspections were always quite satisfactory.

With respect to aspects of quality control other than sanitation, I have found that most problems in my former industry as well as those in my present association are basically not those of a regulatory nature of prime concern to FDA. There are exceptions, such as control of pesticide residues and food additives where FDA is, and must be, heavily involved. These topics will be discussed in

another session. The preponderance of other quality control problems in my experience relate to degree of excellence and internal, packer specifications, not legal requirements. This finding will vary with the individual packer or industry. For this reason I have selected for my opening statement, comments on two points of more general application and will await the later question and answer exchange to emphasize any specific problems.

One of the most frustrating problems in any large organization, be it governmental or industrial, is the difficulty in maintaining speed of communications. In some cases, slowdown comes about because of unnecessary red tape. In other instances, it is failure to specify authority for decision at a low enough level. In other cases, it is failure to set up sufficiently clear standards by which decisions can be made without highly personalized considerations.

We know that inability to attain a prompt reply often deters one from asking a question. This truism can be observed in one's own personal life as well as in the industrial or governmental sectors. The promise of a quick response is often sufficient to encourage a person or a company to make an inquiry prior to committing himself to a course of action. In the past, speedy replies from FDA have not always been the rule, thus bringing about a fairly common belief among many industry people that FDA at times moves rather slowly. This judgment is not necessarily deserved at the present time since all thoughtful people realize that complex problems often require thorough research and consideration before decisions can be made. Nevertheless, it will require continued pressure by FDA management to correct the past impressions if a reputation for expeditious action is to be maintained. The need to get prompt and meaningful replies is even more important if industry is to be encouraged to make preliminary inquiries so as to avoid faulty approaches to problems. These problems, of course, are in every area of FDA's activity, including sanitation and quality control of food products. The recent reorganization of FDA and the emphasis being placed on voluntary compliance and self-regulation make it mandatory to expedite replies to each inquiry in clear, straightforward language.

Similarly, where factory inspections have been made and samples taken for analysis, every effort should be made to advise the packer of analytical results promptly. Greater motivation and probably better compliance will be obtained while the packer's interest is still aroused by the inspection. Even where samples are found to be

nonviolative, the packer needs, and we believe deserves, prompt advice. We realize that this will not always be easy to do but it should remain a goal where the degree of attainment is checked by top FDA management constantly.

FDA and Industry Workshops

In my somewhat limited contact with food industries around the country I have observed that there is still a woeful lack of knowledge about food and drug matters among food technologists. Much has been done to correct this void but it seems to me that an even more accelerated program is required. One of the approaches which I have long felt useful is the direct or cooperative sponsorship by FDA of workshop sessions in various geographical areas. These sessions should be aimed at middle and supervisory technical management—not the top management nor merely the people who constitute technical liaison with regulatory agencies. Likewise, they could not profitably be aimed at the lowest and most junior technologists or technicians. They should be slanted to working level problems, the real "bread and butter" aspects of food compliance, and not theoretical or philosophical propositions. Sanitation would be a very large part of the program with the balance of time to be split among the other food problems and regulations. The emphasis should be placed on the special interests of the principal industries being serviced in each area.

While most of the regulatory requirements are spelled out in the law, in regulations or in explanatory bulletins, it is still a fact that live (or possibly closed circuit TV) instruction is much more effective in getting points across. I have noted in a recent statement by Shelby Grey that a workshop, perhaps along these lines, has been conducted in recent months, which fact may indicate that this type of program will gain momentum. I hope it will.

As a final suggestion, I would like to turn our conference theme around and instead of the phrase, "What Industry Needs from FDA for Better Compliance," make a suggestion as to "What *FDA* Needs from *Industry* for Better Compliance." In inquiring of a number of associates in industry, including persons from several trade associations, I find that a strong feeling exists that there are many FDA inspectors who are not adequately trained in the technology and problems of industries they are required to inspect. It is not unreasonable to assume that the observation has merit when one considers the recent increase in personnel at FDA. It would be difficult, indeed, to obtain this number of new people who are ade-

quately prepared by experience for so many different industries, both food and drug.

Perhaps industry could be helpful in this regard through the medium of workshops or clinics similar to those mentioned above but oriented toward instruction of new inspectors. They could be directed to specific types of food processes, such as vegetable canning, freezing, soft drinks, etc., and preferably would be geographically dispersed so as to allow all inspectors in certain areas to attend. Industry experts in production as well as in quality control could be responsible for outlining manufacturing procedures, raw material problems, sanitation methods, quality control techniques, packaging concepts, etc. There would be an opportunity for exchange of ideas and I expect there should be "equal time" made available for FDA representatives to express their views if controversial issues were put forward by the industry people.

I realize that such an approach will raise many questions from FDA as well as from industry. In fact, I have no idea whether an industry group or any individual packer would undertake the project. Nevertheless, it is a thought which could work towards better training of inspectors and improvement of their real understanding of industry's problems. There is no doubt but what continual efforts should be made to bring industry and FDA representatives together for discussion of their problems. With real understanding and a mutually cooperative attitude, there is certain to be a better atmosphere for self-regulation and compliance. This is the goal we all seek.

An aspect of control which continues to trouble many food manufacturers is that of fill, or net contents, of containers. In my experience with industry associates I have found much lack of knowledge or misunderstanding regarding requirements for compliance with Section 403 of the Food Drug and Cosmetic Act.

The crucial part of this requirement is that which relates to allowed variation of individual packages from the declared contents according to good packaging practice. The economic impact of container fill is well-known to most manufacturers, particularly those of relatively expensive commodities. Manufacturers suffer from excessive overfill but so do consumers, who ultimately must pay the higher costs. Of course, the ideal situation, for packer and customer alike, is for every package and every lot to contain exactly the quantity declared on the label. Since this ideal goal is simply not practical, the concept of variability has been recognized by FDA. Thus, it is expected that some packages will contain less and some

will contain more than the label declaration. No packages can exceed a reasonable tolerance from declaration and each lot must equal or exceed the declared contents.

While these facts are familiar to all knowledgeable industry people there are many who still have a gnawing feeling that there is a regulatory onus, both federal and state, against any single package whose contents are on the negative side. In addition, there is the fear of seizure and possible publicity when only a few units are concerned but are considered as a lot. Thus, they impose upon themselves, unnecessarily high average fills just to avoid or minimize any individual underfills. Some regulatory individuals may smile at this statement and wonder if this represents theoretical situations or at most, a highly unlikely exception.

On the contrary, I am convinced there are many packers, mostly among the reputable, who practice this unnecessary and uneconomical packaging procedure. While it is perhaps their fault and surely not entirely the fault of FDA, it seems likely that FDA could and should lead the way in clarifying for all industry and regulatory groups, the reasonable and appropriate approach to package contents. FDA is the logical source of such leadership in order to gain the acceptance of the large number of state and local agencies who participate in this type of control. Since so many agencies seem to be involved in food package regulations, it is not surprising that there really are numerous interpretations of net contents requirements, including sampling procedures at the factory level and in the market.

As an example, I have been told of an instance where an inspector deemed a commodity to be violative due to underfill when only one or two containers from a retail store were checked. In another instance, slightly underfilled containers were said to be violative before a local inspector had checked out the proper method for measuring contents of frozen concentrate cans or had considered fully the lot size which might be involved. In these cases, complete container fill data for the lots were available showing a high degree of control and statistical evidence of meeting what could be considered reasonable fill criteria. Unfortunately, these incidents are not just exceptions; similar incidents have occurred too frequently.

My recommendation is that FDA clarify through all appropriate media the basic rules of container fill which should govern all packaged foods moving in interstate commerce. These interpretations would allow reasonable variation in individual packages and reasonable definition of lot sizes. Such regulations will afford honest

packers an opportunity to maintain as economical operation as intended by the law. On the other hand, uniform rules, when properly and equitably enforced by all agencies, whether federal, state or local, would effectively prevent the occasional negligent practices (or purposeful cheating) of those who are not among the majority of packers trying to do an honest job. All guidelines should be founded on sound statistical concepts and all educational material should stress the benefits obtained when packers use modern control procedures and maintain filling equipment in first-class condition. The customer is assured of a fair shake for his money; the packer achieves highest possible yield with greatest freedom from costly over or underfills; and regulatory agencies may safely check a minimum number of containers to assure themselves of compliance. **[The End]**

Comments by KARL F. LANG, Panelist

Mr. Lang Is Manager of Quality Control, H. J. Heinz Company.

I WELCOME THE OPPORTUNITY to be a part of the Sanitation and Quality Control Workshop this afternoon. In preparing for the workshop, I reviewed the organizational charts for the Food and Drug Administration as well as functional statements for the various bureaus, divisions and branches. I am impressed with the broad program of promoting voluntary compliance and cooperation between the public, the food industry, and the FDA through educational and informational activities.

The industry information and advisory opinions branches of the Bureau of Education and Voluntary Compliance have been most helpful in furnishing information on FDA views and policies, interpretations, contemplated practices and procedures.

No one will disagree that information and education are essential tools in promoting industry compliance and providing consumer protection. We welcome such an approach to attaining the objectives of protection for both consumers and honest business.

With such a strong desire on the part of the FDA to be of help wherever possible, we pose this question: "What does the food industry need further from the FDA for better compliance?"

Repeatedly, we have heard representatives of the FDA say: "Our inspectors do not get into food factories often enough to make complete inspections, thus inspections of pertinent records are necessary when they do have the opportunity. They must have access to com-

plete and accurate information about such things as manufacturing processes, manufacturing controls, laboratory controls, conditions of storage and coding and distribution of finished products."

I am sure I speak for the majority of reputable food manufacturing companies when I say we welcome FDA inspections. In my own company, we encourage visitors every working day of the year to come and visit our plant and see our operations. This is good business —excellent advertising. We want consumers to ask questions about our manufacturing processes and controls, storage of ingredients and finished products as well as their distribution. There is, of course, a point where one must "draw the line" to protect "know-how" which gives one a slight competitive edge in a very competitive, low margin business.

Good sanitation practices, bacteriological control of ingredients and assurance of adequate processing is mandatory at all times. One does not promote such activities sporadically or to impress the occasional food and drug inspector. In process control, quality checks, laboratory checks on field crops as well as processed ingredients are accepted responsibilities regardless of whether an FDA man makes an appearance or not. We cannot afford to neglect such responsibilities.

Necessary Programs and Practices

A quality control program, coordinated with a sound sanitation program prescribed and enforced by management is the answer to voluntary compliance—a continued program of education within the food industry to make individual employees and supervisors conscious of the desire to produce *clean food,* in a *clean factory,* with *clean people.*

In light of potential public health problems, the food industry must maintain constant vigilance of sterilization practices. These include: (1) adequacy of the process used; (2) proper retort installation; (3) ingredient control (bacteriological); (4) headspace control; (5) initial temperature; (6) retort operations (mechanical); (7) cooling water (bacteriological); (8) pH control; (9) packaging specifications; and (10) personnel education.

Again these control points are not for the occasional viewing by a food and drug inspector, but require a continual day by day, hour by hour watching. That is our responsibility to safeguard the consumer.

What industry needs most from the FDA is a continuance of their program of education. Helping industry as well as consumers to better understand the need for adherence to tolerances, is essential. Coopera-

tion with the food industry in programs directed at improving consumer protection, and less concentration on its enforcement and police power activities, are in order. Granted, the industry can educate itself so as to be better able to understand and perform its function of bringing safe and properly labeled foods to the consumer. The Food and Drug Administration—National Canners Association workshop session such as was held this past July here in Washington is a fine example of what can be done to insure voluntary compliance.

We would like to suggest the FDA disseminate their answers to industry inquiries without identification of the parties concerned. This would help to clarify matters of policy and interpretation of legislative procedures which more than one processor may have had in mind but hesitated to ask. Promote a better informed food industry. This is now being done, in part, by established food and drug publications.

There is a definite need for better inter-government agency agreement on certain interpretations. For example, differences of opinion regarding the use of weight net contents versus volume net contents. Although two departments report to the same government agency, still they are at odds as to the method to be used for labeling the same type products.

Clearly defined tolerances for mold and insect fragments would be of great help to food processors in their compliance with established regulations. The "grey area" between announced spray residue limits and unannounced insect tolerances needs to be clarified. Large producers of food products spend considerable sums of money on testing both for spray residue and insect fragments. Then one doesn't know just what to do when he obtains this data.

Another area where the food and drug inspector can help a great deal is in the attitude he expresses at the time of his visits to a food plant. For the most part, inspectors will generate a feeling of helpfulness, assistance, cooperation, etc.—a sense of "what can I do to help you? Let's see what we together can evaluate so that you can do a better job of compliance."

On the other hand, you will encounter the inspector with a so-called "chip on his shoulder." An attitude of "Let's see what we can pin on this guy. Let's give him the works."

The FDA could promote better compliance by instructing inspectors to approach factory inspection as an opportunity to assist, to help and to educate. In so doing, the food industry would look to him with open arms and a feeling of "glad you stopped in." **[The End]**

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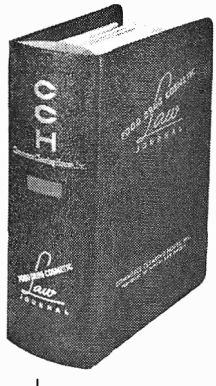

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