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

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

1964 FDA-FLI Conference. — The Eighth Annual Joint Conference of the Food and Drug Administration and The Food Law Institute, Inc., was held on November 30, 1964, at the Marriott Twin Bridges Motor Hotel in Washington, D. C. The purpose of the conference was to promote understanding of and voluntary compliance with the nation's pure food and drug law. The day-long session was devoted to industry information, consumer education and voluntary compliance. This issue of the JOURNAL contains eight of the papers which were presented at the morning session of the conference.

Shelbey T. Grey, deputy director and acting director of the Bureau of Education and Voluntary Compliance, Food and Drug Administration, called the meeting to order. *Frederick Brown Harris, D. D.,* Chaplain of the United States Senate, delivered the invocation. Welcoming remarks were made by *Edward W. Dempsey,* Special Assistant to the Secretary (Health and Medical Affairs), United States Department of Health, Education and Welfare. These remarks are on page 636.

FDA Commissioner *George P. Larrick* presented the keynote address appearing on page 638 and *Franklin M. Depew,* President of the Food Law Institute, offered a response from the Institute, which appears on page 643.

"An Ounce of Prevention" regarding voluntary compliance was discussed by Mr. Grey in his comments which begin on page 648. *Richard L. Hall,* director of research and development, McCormick & Company, Inc., spoke on "Self-Regulation in the Food Industry," after which *Robert P. Parker,* general manager, Lederle Laboratories Division, American Cyanamid Company, evaluated "Self-Regulation in the Drug Industry." Mr. Parker summarized industry's attitude toward self-regulation in this manner: "we had to be responsive to the public interest in our own self-interest." These remarks begin on pages 653 and 662 respectively.

The first of four speakers on the subject of "Science Promotes Voluntary Compliance" was *O. L. Kline,* who discussed the nonmedical viewpoint. Mr. Kline is the FDA's Assistant Commissioner for Sciences Resources. His paper begins on page 669. The papers by *Joseph M. Pisani, Austin Smith* and *Robert M. Schaffner* on this topic will appear in next month's Journal, along with papers by *William W. Goodrich* and *W. Howard Chase* which concluded the conference.

An index appears on page 674 of all the 1964 articles, according to author and title. Articles are also listed under appropriate general subject headings.

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Food·Drug·Cosmetic Law
Journal

Welcoming Remarks

By EDWARD W. DEMPSEY

Dr. Dempsey Presented These Introductory Remarks at the Eighth Annual Joint Conference of the Food and Drug Administration and The Food Law Institute, Inc., in Washington, D. C., on November 30, 1964. He Is Special Assistant to the Secretary (Health and Medical Affairs), United States Department of Health, Education and Welfare.

I AM GLAD TO WELCOME YOU in the name of the Secretary, who regrets his inability to be with you. It is especially pleasant for me to be able to meet with such an illustrious gathering of government, consumer and industry representatives. As many of you know, I have been Special Assistant to the Secretary for Health and Medical Affairs for only a short time, and so your problems and discussion of how to deal with them are not only of keen interest, but also of immediate importance to me.

I note that the themes of your past Food and Drug Administration-Food Law Institute jointly sponsored meetings have been timely and current. I believe that conferences of this type go a long way toward better understanding, cooperation and mutual appreciation of common problems and goals. This year's theme of consumer education, industry information and voluntary compliance is again timely and provocative. Last year, the Secretary noted the importance of voluntary compliance, and mentioned the formation of a new bureau to signal its emphasis. We are all interested in doing a better job, producing better and safer products, and promoting wider consumer understanding and confidence in our output.

Consumer education and information are important facets of the President's consumer interest program and so your program today will, I am sure, develop important answers to many of the questions consumers ask about the quality, wholesomeness and safety of foods, drugs, cosmetics and related products. I am sure, too, that industry,

so ably represented here today, will emphatically express its needs from government in order to do a better job of complying with the law.

Since we all share the common goal of need, acceptance and confidence in the field of production, distribution, and use of foods and drugs, it behooves us to work together to accomplish these objectives.

I am particularly impressed with the visual exhibits that constitute a portion of this program because they help to demonstrate ways and means currently in use to educate, inform and promote voluntary compliance. I urge all of you to take the time during the day to view these exhibits and become familiar with their message.

[The End]

PLAN FOR ENFORCEMENT OF REGULATIONS ON PRESCRIPTION DRUG ADVERTISEMENTS

A plan for enforcement of the prescription drug advertising provisions of the Kefauver-Harris law has been put into effect by the Food and Drug Administration, Department of Health, Education and Welfare. In enforcing the requirements of the act the FDA will seek to determine whether a fair balance exists between the information on effectiveness and that on side effects and contraindications.

The Bureau of Medicine will monitor professional journal advertising for prescription drugs. The kinds of advertising that may be violations of the act include the following: extension or distortion of the claims for usefulness beyond that approved in the final printed labeling; featuring of a quote from an article in a way which misleads by improperly implying that the particular study is representative of much larger and general experience with the drug; the selection of poor quality research papers making statements favorable to the product while ignoring contrary evidence from much better research; quotation out of context of a seemingly favorable statement by an authoritative figure but omission of unpleasing data from the same article; quoting from an obviously authoritative source while failing to quote from other differing experts in the same field with the result that a properly balanced view is not given; featuring data from papers that report no side effects, but failing to quote from others that do; and, continuing to run ads which are constructed from data previously valid but rendered obsolete or false by more recent data.

The Bureau of Scientific Standards and Evaluation will furnish scientific evaluation to the Bureau of Medicine; the Bureau of Education and Voluntary Compliance will continue to answer specific questions from industry regarding prescription drug advertising; and the Bureau of Regulatory Compliance will set in motion such corrective actions as may be required to deal with violations of the advertising provisions of the Kefauver-Harris Drug Amendments.—FOOD DRUG COSMETIC LAW REPORTS ¶ 80,096.

Cooperation in Promoting Voluntary Compliance

By GEORGE P. LARRICK

Mr. Larrick Is Commissioner of the Food and Drug Administration.

WELCOME TO THE EIGHTH ANNUAL EDUCATIONAL CONFERENCE sponsored jointly by the Food Law Institute and the Food and Drug Administration. These meetings provide a valuable forum for the discussion of our mutual problems in consumer protection and also are in agreement with the Administration's policy. As you know, President Johnson is very interested in the welfare of American consumers. In February, he sent a message to Congress in which he not only outlined the Administration's stand, but also described some actions taken to strengthen the voice of the consumer in the topmost levels of government. On January 3, 1964, he appointed Mrs. Esther Peterson as his Special Assistant for Consumer Affairs and, in addition, established the President's Committee on Consumer Interests. Among other things, he said it was the desire of his Administration "to fight side by side with enlightened business leadership and consumer organizations, against the selfish minority who defraud and deceive consumers, charge unfair prices, or engage in other sharp practices."

The FDA-FLI meetings began in 1957 at the suggestion of the late Charles Wesley Dunn. They provide a sound structure for communication between the regulated industries, consumers and FDA. Frank Depew has worked very closely with our people in developing today's program.

Topics Discussed at Past Conferences

At the first FDA-FLI Conference in 1957, I reported on our philosophy, organization and operations. Recognizing that as a regulatory agency we were committed to taking legal actions where substantial violations were involved, I stressed then, as now, the importance we attach to voluntary compliance.

We continue to seek maximum compliance with the law with a minimum of court actions. Preventing violations is more economical and provides better protection for the consumer than to have to institute legal actions after violations have occurred. Voluntary compliance is fostered by two-way channels of communication. These conferences are an important means to this end.

The 1958 conference covered the complicated legal and scientific aspects of the Food Additives Amendment.

The 1959 conference continued discussion of food additives as well as other major problems arising from the impact of modern food technology.

In 1960, the Color and Food Additive Amendments plus the new Federal Hazardous Substances Labeling Act were the center of attention. The FDA Consumer Consultant Program was also discussed.

Pending drug legislation increased the emphasis on these problems during the 1961 meeting.

The 1962 conference was a departure from the earlier meeting in that it had as its topic a discussion of the broad areas of our mutual interest, rather than specific problem areas.

In 1963, Deputy Commissioner Harvey presented a description of the 1963 reorganization. He described FDA's two new bureaus—first, the Bureau of Education and Voluntary Compliance, which deals with consumer education and helping industry understand what the various laws require. He also described the Bureau of Scientific Research, which is responsible for our basic scientific research program. This bureau is now headed by Dr. William H. Summerson, who brings to his new task many years of broad experience in university and government research.

The 1964 theme—industry information, voluntary compliance, consumer education—represents three interrelated ways of increasing consumer protection on a voluntary basis. The success of this approach depends upon constructive relationships between industry, consumers and FDA based upon a knowledge of each other's needs, functions and responsibilities.

Much of the value of these earlier conferences developed during the question and answer periods, during which our representatives answered numerous questions. These questions and the answers were publicized by the Food Law Institute. These periods did achieve a

better understanding of our policies on the part of both industry and consumers. This year *we* are asking questions. We want to know what industry and consumers think our agency can do to promote an even higher level of voluntary compliance so that our mutual goal of the best protection possible for American consumers can be achieved.

What FDA Is Doing to Promote Voluntary Compliance

A promising approach in promoting voluntary compliance has been the increasing use of FDA-industry workshops conducted by our Division of Industry Advice. These workshops provide industrial and trade managers with an intimate view of our operations and a personal acquaintance with FDA's top experts in our specific fields of endeavor. We hope that these workshops will not only help you to understand, but also better appreciate the background and intent of our regulations. Participants may then be motivated to "spread the word" of the value of voluntary compliance in their firms and in their trade associations. To maintain this constructive attitude, the Industry Information Branch either provides to or helps trade associations plan the content of leaflets, slides and other visual aids dealing with specific compliance problems.

Our Consumer Education Program is based upon the premise that an informed consumer can, for example:

(1) Protect children against poisonings in the home,
(2) Use drugs safely and effectively,
(3) Choose health services wisely,
(4) Avoid phony cures and fake medical devices,
(5) Steer clear of frauds and cheats, and
(6) More accurately appraise products that they buy.

The Division of Consumer Education has developed radio and TV public service announcements, school information packets, slides, movies and exhibits, as well as a series of publications designed to inform the average consumer, as well as those consumer groups, of special problems. These materials are on display as part of this conference's exhibit program. Many are used by our consumer specialists and consultants in our FDA districts.

Of particular significance is the use of some of these materials by industry groups in their education programs.

Because all FDA units at headquarters and in the field engage in some activity which promotes voluntary compliance, we can only mention a few.

Scientific Research and Communication Are FDA's Major Tools

Our major tools in promoting voluntary compliance are scientific research and communication. For instance, the Bureau of Scientific Research gives direct assistance to industry through pioneering research on new food or drug contamination problems. When an industry is confronted with a problem involving the safety of its products, such as botulism in smoked fish, instituting self-regulation is not a matter of choice but of necessity. The Bureau of Scientific Research, as well as all units of the FDA, works cooperatively and closely with scientists in industry and in universities as soon as some health problem is discovered. Samples, standards, and know-how are shared, so that reliable methods of detecting the contaminant are developed quickly and can be applied by both industry and government laboratories.

Our field districts spend considerable time speaking to industry groups on compliance problems. In the past nine months, our district and headquarters personnel delivered 288 speeches before various industry groups.

Because a technical knowledge of industry operations and problems is more difficult to obtain with the increasingly complex technology of food and drug production, FDA accepted the invitation of the National Canners Association to conduct workshops in canning technology for FDA inspectors. The value of such programs is obvious.

FDA promulgates many regulations that have the force and effect of law. Usually they are first published as proposals so that all interested persons can make their views and constructive criticism available to us. Mr. Goodrich will outline why we believe regulations are aids to voluntary compliance. Based upon this belief, we provide reprints of these regulations to the industries concerned and other interested parties free of charge. With the increased importance of premarketing clearance of food and drugs, regulations have become basic and indispensable guides to the regulated industries. Considerable time and effort are being given to all FDA units which prepare them to make them as clear and valuable as possible. When necessary, we issue press releases, speak before industry groups and prepare other aids to promote better understanding of the regulations.

The new approaches to promoting voluntary compliance which are being progressively adopted are possible only if we have the cooperation and support of foresighted trade association and industry leaders. We look forward to continued cooperation with industry and consumer leaders so that all of our efforts toward voluntary compliance will increase the level of protection afforded consumers. When you have suggestions for further innovations in achieving greater compliance, do not hesitate to let us know. We welcome your thoughts and ideas. **[The End]**

MEMBER OF FOOD COMMISSION DESCRIBES COMMISSION'S TASK

Congresswoman Catherine May, a member of the recently established National Commission on Food Marketing, told a meeting of the National Food Brokers Association that the Commission's task will break down into three main parts. They are (1) to study the current situation in the food industry and the trends affecting it, (2) to appraise those facts and trends in order to understand how they affect efficiency and competitiveness, and (3) to reach conclusions regarding the kind of food industry that the nation should have and the policies conducive to maintaining this sort of industry.

Representative May went on to say that the Commission will develop information by three principal means: (1) by bringing together a large amount of data relating to the food industry but now scattered through government agencies, trade sources and universities; (2) by collecting necessary data from firms in the food industry; and (3) by holding hearings in Washington and other areas of the country.

All major sectors of the industry will be studied, including such subject matter areas as the processing and procurement of beef, poultry, dairy, milling and baking, fruits and vegetables, and other foods. Studies will be made on a specific commodity basis and will deal with competition and trade practices in wholesaling, processing, procurement, vertical integration, and methods of buying from farmers. Representative May commented that throughout its studies, the Commission must focus upon efficiency in the performance of necessary functions and the nature of competition at all stages of marketing.

The Commission's staff, consisting of economists, research personnel and a small legal group, will go about its duties in a true spirit of inquiry, without prior judgments as to what the facts are. All segments of the industry will have an opportunity to be heard, and studies made within industry itself will be welcomed.

Concluding her remarks on the work of the Commission, Representative May stated that "the food industry is our most important industry . . . and it is changing for reasons that are not widely and thoroughly understood. Certainly, the need for a study of the industry arises, not from any major failures on its part, but from its great significance to the nation in a time of rapid economic change."

Opportunities for Cooperative Enforcement

By FRANKLIN M. DEPEW

Mr. Depew Is President of The Food Law Institute, Inc.

I BELIEVE YOU WILL AGREE that Commissioner Larrick's keynote address has indeed established the framework wherein those of us assembled here may hope through this conference to effectively further understanding of and voluntary compliance with our food and drugs laws. It is now my privilege to respond on behalf of The Food Law Institute, the co-sponsor of this meeting.

The Food Law Institute was founded some 15 years ago by the food industry as a contribution to the national welfare for the protection of the food economy and the public health. It was established in the belief that we could secure better compliance with our food and drug laws, enacted to assure the safety, purity and integrity of these vital products, if government and industry representatives were better trained not only in the intricacies of the laws' requirements, but in the philosophy of their enforcement as well. This belief presupposed that good faith existed on both sides, since without conferring and discussing with mutual respect, no lasting resolution of differences of opinion may be expected. We in The Food Law Institute are persuaded that the results to date in improved understanding between the consumer, government and industry, justified this belief. They confirm the high American tradition that the self-interest of industry is best served by an altruistic regard for the public welfare.

The FLI educational program has consisted of university instruction in the food and drug law (principally by law schools), which is wholly or partly underwritten by the FLI, the publication of the authoritative FLI Series of books on these laws, the editing of the FOOD DRUG COSMETIC LAW JOURNAL published by Commerce Clearing House, and the sponsoring of educational lectures, seminars, symposiums and conferences on various aspects of these laws both in the United States and throughout the world. The most important of these conferences is that held jointly each year with the Food and Drug Administration, of which this is the eighth.

But what the FLI has done in the past, and is now doing, is only a prelude to what it can and should accomplish. During the years since the FLI was founded the responsibility for consumer protection has expanded at all levels of government and within industry itself. To realize the opportunities before it, the FLI must have the deserved support of additional food manufacturers and other manufacturers related to the food industry, who thus recognize their primary social responsibility to this important public law governing their industry. We believe that the FLI's record in the past 15 years merits that support.

Panels Will Make Recommendations

In the light of its history and purposes it could be expected that we in the FLI would especially welcome that part of the reorganization plan for the FDA approved by the Honorable Anthony J. Celebrezze, Secretary of Health, Education and Welfare, on November 1, 1963, which created a separate Bureau of Education and Voluntary Compliance to improve consumer and industry information, education and voluntary compliance. This new bureau has been set up to be co-equal to, but entirely independent of, the Bureau of Regulatory Compliance which is charged with regular law enforcement responsibilities. We believe this action will prove to be a significant step forward in achieving a better balance in the FDA's program of consumer protection. Whether this prediction will prove accurate will, we believe, depend to a large extent on the recommendations made by the five expert panels meeting during this conference to discuss the best ways of facilitating and elevating consumer information and education and the promotion of voluntary compliance. These panels are made up of public-spirited men and women who are greatly interested in having this experiment in cooperation succeed. Their thorough discussion of the problems involved should be most helpful in providing guidance for future action by this new bureau.

Consumer Education

I now venture to speculate on some of the matters which may engage their attention. First, there is the continuing and difficult problem of creating an enlightened public. There would appear to be no difference of opinion between industry and the FDA as to the need to do a successful job in educating the public. Numerous industry programs are now in operation designed to enable the consumer to buy and use products more intelligently and effectively. As examples, Grocery Manufacturers of America, Inc., (the national association of

the food industry), and the National Canners Association have endeavored for many years to educate the consumer, and in turn to educate industry about consumer views. Both organizations have worked closely with the Division of Consumer Education of FDA and its predecessors. This division which is now a part of the new Bureau of Education and Voluntary Compliance, has been set up with three branches: Consumer Information, Consumer Consultant and Consumer Survey. The efforts of industry and the FDA are supplemented by the activities of a number of consumer organizations. It would appear that with all this educational information available to her, the consumer should be informed. However, sometimes the maze of rules, regulations and interpretations—not to mention required or suggested label statements—are in such form as to be confusing to the ordinary buyer. Sometimes the use of technical terms has created problems in communication. Where this is so, appropriate action should be taken.

A major stumbling block to the solution of some of these problems arises from a conflict of opinion between industry, government and consumer organizations as to the interpretation to be put on the consumer views which are expressed. It has been found that it is difficult to determine the expectations of the "average" consumer, and even more difficult to determine whether that "average" consumer has been or will be misled. I sometimes wonder if an "average" consumer exists. It has been almost impossible to deduce from the many conflicting voices which claim to represent the consumer just what the actual consumers do want or need in order that a product meet their expectations in respect to labeling, packaging, identity and quality. Consumer surveys have usually failed to bring any clear-cut conclusions where they have been used. While the areas where these difficulties exist may be small compared to those where labeling, etc., are considered to be satisfactory by all, this does not make it any less urgent that they be solved. I hope that this afternoon our Consumer Panel will come up with some suggestions as to how to find, and carry out the consumer's views in these areas in such a way as to enable her to have a true freedom of choice.

Hindrances to Full Cooperation Between Industry and FDA

It is in the field of cooperation in education of industry itself that some industry leaders feel that the FDA has failed to a large degree in the past. FDA's advisory opinions have frequently been so conservative that the company observing them has found itself outstripped by its noncomplying competitors, who have placed a different

interpretation on the laws' requirements, without any action being taken by the FDA. This past practice of the FDA has often placed those who are unaware that the FDA will not enforce the law on the basis of such advice at a great disadvantage. Another of FDA's policies of which industry is critical, is that of refusing to approve additive petitions unless the labels used on the product which contains the additive are approved. This sometimes means the label must be substantially changed from those used in the past. Industry feels that where the FDA has not challenged the label statements in the courts and shows no intention of challenging similar statements of competitors in the future, the company which has proved the safety of its additive should not be penalized because of its innovation.

Industry accordingly feels that advisory guidelines should at least approach, if not be identical with those where regulatory action will be taken. This is also true with respect to official tolerances and administrative tolerances.

Another hindrance to full cooperation between industry and the FDA is the possibility that the information given may be used against the informant. Industry has sometimes hesitated to make a frank and fair disclosure of the facts because of the possibility of self-incrimination. Industry needs a firm and convincing statement from FDA that the policy of this new bureau is to prevent violations of the law, rather than to punish violations after they occur, if they are to expect disclosure in a spirit of mutual confidence and respect. A number of the states have successful programs based on education where self-incrimination is not recognized as an enforcement tool. These programs have improved public relations between industry and the enforcement authorities and have decreased the number of court cases needed for enforcement. Surely, this new FDA Bureau of Education and Voluntary Compliance should operate on a similar basis.

If these gaps between intention and achievement are courageously reviewed by our panelists during this conference, we may expect to get some recommendations from them which will go far toward furthering the fair and efficient administration of this law, by both government and industry, which should provide a sincere encouragement to industry to strive even harder to assure full compliance with the law's intent.

Another useful feature of this conference is that it will enable both FDA and industry to describe and to show by exhibits the steps each is taking to secure the desired objective of compliance. Hope-

fully this should lead to a greater correlation between the respective programs for the common good of all.

Everyone recognizes that complete government regulation is not economically feasible nor socially desirable. It follows that the best way for government and industry to perform their respective functions is in a cooperative effort. This will enable FDA to concentrate on the habitual, flagrant offender, who should be severely punished as an educational lesson for others who might wish to do likewise.

We in the FLI have high hopes that the guidelines resulting from this conference will establish a new era of FDA-industry cooperation. Whatever the outcome, we pledge ourselves to continue our efforts to create a better understanding by all of the philosophy and requirements of our food and drug laws. **[The End]**

FOOD STANDARDS AND THE CONSUMER

"The two primary drives in the standards area today are that of the consumer for more informative labeling on the standardized article and that of the food manufacturer for more freedom in his choice of optional ingredients—freedom from the so-called 'recipe making' approach and its alleged stifling effects on progress in the food industry." This view was expressed by M. R. Stephens, Assistant Commissioner for Regulations of the Food and Drug Administration, at a symposium on "The Legal Basis and Regulatory Use of Food Standards." The symposium, presented by The Food Law Institute, Inc., the Graduate School of Public Law of George Washington University and the Food Protection Committee, Food and Nutrition Board, National Research Council, National Academy of Sciences, was held on December 1, 1964, in Washington, D. C.

In discussing consumer demands for more and more ingredient declarations, he declared that "we should be able to provide in standards more freedom of choice for the use of optional ingredients so long as the consumers who purchase such foods under their standardized name can have assurance that they will get what they may reasonably expect to receive when purchasing them. Any freedom of choice beyond this point would make the whole standard-making process a futility. The problem in a nutshell is whether it is in the public interest to give the manufacturer additional flexibility on optional ingredients, while holding him to more rigid labeling requirements and all the while surround the process with sufficient safeguards to maintain the identity of the standardized article. We think so."

An Ounce of Prevention

By SHELBEY T. GREY

Mr. Grey Is Deputy Director and Acting Director of the Bureau of Education and Voluntary Compliance, Food and Drug Administration.

THE OLD ADAGE that an ounce of prevention is worth a pound of cure has, over the ages, been applied to many situations and conditions. My discussion with you will apply this gem of wisdom to compliance with the law.

We believe there are two ways to comply with the law—(1) voluntarily, which means adequate self-regulation following guidelines furnished for this purpose, and (2) involuntarily, or by enforcement, using the tools provided by the statute; that is, seizure, injunction, and prosecution.

This principle was reflected in the Commissioner's thinking, concurred in by the Secretary, when the Food and Drug Administration was recently reorganized. Two separate but equal in stature Bureaus were developed—(1) the Bureau of Regulatory Compliance and (2) the Bureau of Education and Voluntary Compliance—to deal with and handle these functions and responsibilities.

Now there is really nothing new about this because FDA has always believed in compliance with the law. The Commissioner has maintained an "open door" policy with industry for years making his time and that of his staff available to discuss all phases of compliance, give advice and guidance, and offer help to anyone seeking it. On the other hand, we have, and will continue to unrelentingly invoke the legal remedies provided by the statute to control violative actions by that small proportion of the industries which, through negligence, ignorance or deliberation ignore the requirements of the law to the detriment of the consumer and the ethical manufacturer.

Activities of the Bureau of Education and Voluntary Compliance

I represent the Bureau of Education and Voluntary Compliance, responsible for planning and conducting a broad program of promoting

voluntary compliance and cooperation between the public, the regulated industries, and FDA through educational and informational activities and programs.

We initiate programs to educate and inform consumers, and provide the food, drug, cosmetic and related industries subject to regulation with the FDA's views on policies, interpretations, contemplated practices and procedures to further and promote voluntary compliance and self-regulation. We also plan and conduct special and routine surveys and studies to determine consumer attitudes, interests, and values and industry trends and attitudes. We are responsible for the development and utilization of all available and applicable modern educational and informational techniques to attain our objectives.

Both government and industry are progressively devoting more time and attention to consumer wants and needs. This is natural since we are all consumers in one way or another and are all vitally interested in anything and everything that affects our health, welfare or pocketbook.

Division of Consumer Education

My Bureau has a full Division of Consumer Education responsible for planning, developing and executing an intensive educational and informational program, on a nationwide basis, to advise consumers on labeling, packaging, composition, warnings where necessary for safe use, and other essential information consumers need to become more informed and better advised. The underlying principle of our consumer education program is that an informed consumer needs the least protection by the government and is best able to assume his responsibilities as a citizen in our increasingly complex society.

Specifically, we believe that the informed consumer is best able to: (1) buy foods wisely; (2) use drugs safely and effectively; (3) protect children against poisonings in the home; (4) choose health services wisely; (5) avoid phony cures and fake medical devices; (6) steer clear of frauds and cheats; (7) think critically about claims in labeling and advertising; (8) evaluate information about foods, drugs, cosmetics, food additives, and pesticides; (9) participate in governmental processes, such as the promulgation of food standards; and (10) assist others in getting the most benefit from consumer protection laws enacted by the Congress.

Recent studies show that the expenditure of the consumer dollar is moving more and more into the hands of the young consumer. By next year, 40 per cent of the total United States population will be

under 20 years of age! Today, there are 25 million pre-adult consumers in the population and by 1970 there will be 28.8 million. Today, over 40 per cent of all brides are teenagers—more wives have their first baby at age 18 than any other age and one of every six teenage wives has two or more children.

Americans over 65 today total 18 million, and the size of this segment of our population is increasing at the rate of 2 million each year!

America today has a hard core of 20 per cent of its population lacking income sufficient for minimum standards of health and decency. Slightly up the income ladder is an even larger group having a barely sufficient income. It is important to you as responsible members of industry, and to us as government, that these and other stratified segments of our population have the information and help they need to spend their meager funds wisely.

Compliance by Industry

We believe that most American manufacturers of foods, drugs, cosmetics and related products have the scientific knowledge, the technical equipment, and the will to produce products which meet both the spirit and the letter of the law; that most American manufacturers recognize that consumer interest and producer interest are identical, and that practices adverse to consumer interest are likewise contrary to industry interest; and that most American manufacturers are making sincere and effective efforts to meet all legal requirements, not only because they are the law but because it is the right thing to do.

Our industry information program has as its goal the assurance that all of the regulated industries know what the law is, what it requires, what it prohibits, and how it applies to them as firms and as individuals. What does compliance mean to you? The dictionary defines the word as the "act or practice of yielding, as to a desire, demand, or proposal." This definition can be parsed to define both voluntary and enforced compliance since the act or practice of yielding, as to a desire, is applicable to those who *want* to comply; whereas the act or practice of yielding, as to a demand, applies to those who require an order or a demand from a court or some similar authoritative body before they comply.

Please bear in mind that we live in a regulated society and that one individual's rights stop where another's begin. What are the con-

sumer's rights? They have been defined by the President of the United States as: (1) the right to safety, (2) the right to be informed, (3) the right to choose, and (4) the right to be heard.

The theme of this meeting is to explore, with you and consumers, ways and means by which these rights are not jeopardized or forgotten by you or us. We must share the responsibility of assuring consumers an adequate and safe supply of wholesome, potent, nutritious, and properly labeled and packaged foods, drugs, cosmetics, and related products.

What does compliance cost? What price do you place on consumer confidence in your products? You know as well as I do that this is a priceless ingredient and that it is necessary for *continued* success. As the great showman Barnum once said "You can fool some of the people all the time; all of the people some of the time, but you can't fool all of the people all of the time."

How much is a pound of cure? I lack data on how much an individual seizure, injunction or prosecution case actually costs industry or the claimant or firm involved, exclusive of publicity, loss of good will, etc., but I know that it costs the government from a few hundred dollars for a relatively simple case all the way up to several hundred thousand dollars for a complex and often long, drawn-out regulatory action.

Visual Aids for Consumers and Industry

How much is an ounce of prevention? We recently produced for $2,200 a 58-second film with the cooperation of MGM and Raymond Massey, transmitting an important message on drug, device, and food quackery to older Americans. It has been seen by millions on the TV networks. A good movie on "Safe Use of Pesticides" costs $15,000. It tells a vital story to the producers and handlers of our fruits, vegetables, and raw agricultural commodities. It has been shown all over the country, is in constant demand, and will continue to carry its message on the safe use of pesticides for a long time.

We have produced many excellent exhibits on many subjects of compliance for display at industry conferences and meetings at less than $1,000 per exhibit. I could go on with similar examples, but I call your attention to the industry and government exhibits on display as a part of this conference and urge you to partake freely of their informational and educational content. Each is an ounce of prevention!

Conclusion

May I conclude then with the philosophy that an ounce of prevention means that voluntary compliance is in the interest both of industry and consumers and that consumer confidence in the safety, wholesomeness, purity, and legality of foods, drugs, and cosmetics is better gained and more effectively maintained by self-regulation and voluntary compliance than by regulated compliance.

To us this means that the FDA's expertise, its know-how, its views and its policies, as well as its support are available to you for the asking. It means too that all of FDA's vast storehouse of information is available to all levels of consumers to enable them to buy and use foods, drugs, cosmetics, hazardous household substances, etc., safely and with confidence. **[The End]**

DRUGS RETURNED FROM OUTSIDE NORMAL CHANNELS SHOULD NOT BE RESOLD

A wholesaler or manufacturer should not consider favorable the resale of a pharmaceutical product which has been out of normal distribution channels, such as a return by an individual purchaser, FDA Commissioner George P. Larrick stated in an address delivered at the National Wholesale Druggists Association meeting in San Juan, Puerto Rico, November 17, 1964.

In discussing the FDA's policy, Commissioner Larrick said:

"When we were formulating the good manufacturing practice regulations for pharmaceutical manufacturers we considered the desirability of including one section to deal with this matter [the handling of returned drugs]. After thorough discussion of various proposals, we concluded that the reasons for the return of drug products are so diversified that to try to deal with all of the kinds of returns in the form of regulations would be too cumbersome. This situation can best be resolved, in our opinion, by the application of common sense based on an understanding of the kinds of drugs involved.

"There are situations where overstocks are returned in original sealed packages and involve drugs which are quite stable. When the pharmacist returns these to the wholesaler, we see no reason why they should not be resold. Returns of goods subject to deterioration which are obviously shelfworn or damaged by smoke or water should be kept from being marketed again unless and until adequate testing has shown that they are satisfactory and the labeling is both complete and up-to-date.

"We cannot visualize any situation where a wholesaler or a manufacturer should consider favorably the resale of a pharmaceutical product which has been out of normal channels, such as a return by an individual purchaser. The same applies to individual packages which have been opened for any reason. . . ."—FOOD DRUG COSMETIC LAW REPORTS ¶ 80,095.

Self-Regulation in the Food Industry

By RICHARD L. HALL

Dr. Hall Is Director of Research and Development, McCormick & Company, Inc., Baltimore, Maryland.

SELF-REGULATION is a result of many desires and pressures. It exerts itself through many channels and takes many forms. The concept is not new. It is as old as pride of workmanship and respect for law. What is new is the increasing interest and emphasis it is receiving.

In the next few pages, I should like to list briefly the impulses toward self-regulation and the conditions, external and internal, which both make it necessary and control its effectiveness. We will skim quickly over a number of outstanding current examples of self-regulation, as illustrations of the success self-regulation can achieve and of the factors which contribute to this success. The paper will conclude with a suggestion for increasing its scope and effectiveness.

Internal and External Pressures

The pressure toward self-regulation may be internal, stemming solely from a company's desire to produce the best possible product or to provide satisfactory conditions for its employees. Often, however, self-regulation arises externally, from the influence of a customer, or of other companies in the same industry, or, most often, from governmental regulatory action. Even the possibility of regulatory action is a powerful incentive toward adequate voluntary compliance. There is almost no piece of industrial property more valuable than the "company image," and the damage to this image through seizures or other enforcement action is something which most firms will go to great lengths to avoid.

The individual company may regulate itself, often with the help of outside consultants, or it may "police" a competitor, in which case

self-regulation must be taken to mean an inter-company, nonofficial action. Self-regulation is commonly and effectively accomplished through trade associations, about which a great deal will later be said. Significantly, self-regulation may develop because an enforcement agency desires to use the inspection and analytical procedures of a company to extend, to intensify, or partially to replace the inspection activities of the regulatory agency itself.

Conditions Which Necessitate Self-Regulation

Let us consider next the conditions which necessitate self-regulation and control its effectiveness. There are more than 4,000,000 establishments in the United States engaged in the production, transportation, processing, packaging, storage, sales or service of food. All of the federal, state and local inspectors combined could not begin to give a surveillance which, by itself, would be adequate for this number of sites. Any effort to do so would inevitably result in misplaced emphasis, for it is obvious that all locations do not present equal problems or hazards with respect to public health or economic injury to the consumer. They do not present equal hazards, first, because of inherent differences in operations, and, second, because the majority of manufacturers and other operators maintain effective quality control and sanitation programs, both in the public interest and as a matter of good manufacturing practice and internal control. Thus, self-regulation is necessary, both for protection of the public and for the internal requirements of the manufacturer.

Certain of the conditions which determine the effectiveness of self-regulation are internal. One does not recommend self-education for the imbecile, or self-control for the paranoiac. Neither is self-regulation appropriate for the ignorant, the inept or the unscrupulous. Effective self-regulation obviously requires a sincere desire and a competent staff with adequate authority, equipment and good lines of communications.

External influences are equally important. The first of these presents a paradox. Self-regulation has no point if there is total governmental control or regulation. This situation would be abhorrent; but, fortunately, it is also impractical. A safe and adequate supply of food depends upon self-inspection and self-regulation by the producing industries. Yet, self-regulation seldom works in the absence of stimulation and compulsion by government. Governmental agencies must

have the power and the inclination to use their regulatory authority when it is appropriate and necessary to safeguard the public health or to emphasize and stimulate voluntary compliance. But to the extent that the government action enforces regulation, it preempts the field and vitiates or prevents an independent industry effort to do the same thing. Thus, we have the paradox that self-regulation depends for its effectiveness upon the presence of that very government regulation which it should, to the maximum extent, support and often supplant. The proper handling of this paradox requires vision, energy and restraint by both industry and government.

Why Self-Regulation Is Superior

Self-regulation is necessary, as we have seen, and it is possible, as a host of programs to be mentioned shortly have shown. There are several reasons why it can be superior to purely governmental inspection and control. The manufacturer himself is always present; the inspector, in most cases, rarely so. While the manufacturer does not have the broad perspective of an inspector who sees, perhaps casually, many different companies in many different industries, he knows or ought to know his own field of operation considerably better than most inspectors or government technologists. To this special field, his production and technical staff can often devote deeper resources of knowledge and equipment than an over-all regulatory body could expect to apply. Usually a manufacturer will have a far more intensive knowledge of industrial malpractice than an inspector is likely to have. He knows what is often swept under the rug; he knows those things his competitors are doing, which present him with unfair competitive problems. The conscientious manufacturer obviously would like to see substandard competition upgraded or eliminated. The effective harnessing of this knowledge and of the pressures and incentives mentioned earlier should be the objective of a system of self-regulation.

Examples of Self-Regulation in Industry

We have seen that self-regulation is a necessity, and have mentioned several pre-conditions for its success. We know that it offers advantages over enforcement proceedings. Let us now review some examples of self-regulation, as demonstrations of its feasibility, and because they point toward means for increasing its scope and effectiveness. Perhaps the most outstanding example is that of the National

Canners Association. Their laboratories were opened approximately 50 years ago, and the NCA has engaged in an intensive program of research and education since the early 1920s. Many of you are familiar with the processing bulletins and labeling manual it has issued, and with its program of voluntary but rigorous inspection of members' plants. One significant activity of the NCA has brought self-regulation full circle. In 1963, NCA and the Canners League of California ran a training program covering cannery inspection for the Food and Drug Administration and state inspectors. In Rochester, New York, earlier this year, NCA sponsored a similar program for 40 FDA field inspectors and eight FDA office and laboratory workers. In total, their efforts add up to a massive and really noteworthy service, both to members of the industry and to the public.

The milk industry has also made extensive use of self-regulation in spite of the fact that it is probably the most closely regulated of all. Milk is inspected by local, state, and federal agencies. Most governmental inspection in the milk industry is concentrated on pasteurized or fluid milk and relatively little on milk products. Yet, in addition, the milk industry maintains a considerable staff of plant sanitarians and field inspectors on its own. The United States Public Health Service has long championed the need for adequate self-regulation by industry, and its own milk inspection program is designed to make maximum use of inspections by adequately trained industry inspectors.

The milk industry has a long-standing program for developing standards of equipment design. These "3-A Sanitary Standards for Dairy Equipment," developed by joint industry-government committees, are, from the public health design viewpoint, years ahead of comparable equipment in many other areas of food processing.

The baking industry has an effective program covering personnel training, plant inspection, and equipment design begun by The American Institute of Baking in 1946. At present, those bakeries under the AIB system of voluntary inspection or that of the Quality Bakers of America, account for approximately 80 per cent of the nation's production. Twenty-four standards on sanitary baking equipment have been published.

City and State Supported Programs of Self-Inspection

The State of Georgia, New York City and, to a somewhat lesser extent, the city of Baltimore, have begun programs of self-inspection

in the food industry. The Georgia program, after eight months of operation, showed that particular emphasis needs to be placed on training and follow-up in establishments under self-evaluation (self-regulation) if the program is to succeed. A recent report [1] comments:

> It also appears that the study will definitely point toward the use of self-evaluation on a selective basis, limiting the program to establishments which have demonstrated sincere interest and the willingness of management to accept a larger share of responsibility for food sanitation through cooperative action with the health department food service establishment sanitation program.

A particularly significant program of self-regulation is that sponsored by the Department of Defense in companies which are contract suppliers to the Department. Suppliers of nonmeat products are inspected by the Army Veterinary Corps. A Department of Defense Instruction (4155.6, June 15, 1964) states that:

> [T]he Government inspector shall make optimum use of quality data generated by contractors in determining the acceptability of supplies. To the extent that contractor quality data are available and reliable, as determined by the Government inspector, such data shall be used to adjust the amount of Government inspection of products for acceptance purposes to a minimum consistent with proper assurance that the supplies accepted conform to the quality requirements established by the procurement documents.

This program, more clearly than most, underscores the paradox mentioned before. Self-regulation depends for its effectiveness on the presence of some government inspection, but self-regulation to be most effective must be reinforced by a minimum of government intervention.

Self-Regulation in the Flavoring Industry

Another program of self-regulation, along very different lines, is that established by the Flavoring Extract Manufacturers' Association (FEMA) in the field covered by the Food Additives Amendment of 1958. Flavors constitute approximately one-half of the total number of ingredients intentionally added to food. Soon after passage of the amendment, it was apparent to the flavor industry that the petition route of inviting direct government regulation of the food additive situation possessed several disadvantages which the industry did not care to assume. FEMA, therefore, embarked upon an extensive program starting with a survey directed to all flavor manufacturers and

[1] Gibbs, James P., and William A. Hansell, "The Georgia Approach to Self-Evaluation in the Food Service Establishment Industry," presented at the 92nd Annual Meeting, APHA, October 8, 1964.

representative food manufacturers which used flavors. The survey covered all flavoring ingredients and adjuvants reported to be in use and requested, in specific terms, all pertinent data on identity, purpose, usage history and levels, and safety. These data were digested, summarized and reviewed by an expert panel. The panel determined whether or not these ingredients were generally recognized as safe (GRAS) and therefore fell outside the scope of the Food Additives Amendment. This activity received wide acceptance and the express or tacit approval of all related segments of industry and government. The most recent development has been the incorporation by the FDA of essentially the entire FEMA GRAS list into comprehensive regulations governing flavors in which good manufacturing practice is the principal regulatory stipulation. FEMA guide lines, published in draft form a year ago and shortly to appear in final form, will be a major source of information establishing the pattern of good manufacturing practice.

Earlier I mentioned that, in most cases, the manufacturer has available to him knowledge or techniques not available to a government regulatory agency, plus an additional—often compelling—incentive to use them. Again, FEMA experience demonstrates this and also the government's role in the problem. For many years, vanilla extract had been a much abused commodity, and in the late 1950s, was perhaps the most frequently depreciated food product on the American market. This situation presented not only economic disadvantages to the purchaser, but serious problems to the conscientious manufacturer. However, neither federal standards of identity nor an industry program of self-regulation could hope to be effective without objective, accurate methods of detecting adulteration, and of measuring with reasonable precision the vanilla bean solids content of an extract. Methods then available through the Association of Official Agricultural Chemists (AOAC) could not meet this need. As a result of successful research by both the Association and by individual companies, highly sophisticated methods were developed which have since been adopted officially by the AOAC. These methods have almost eliminated the gross adulteration common a few years ago. They made possible the establishment of reasonably effective federal standards of identity. Several cases of FDA enforcement of these standards have stimulated still further industry compliance with the standards. Most of the actual enforcement, however, takes place through the analysis of products by industrial customers and by competitors. This also

occurs in many other industries, and takes advantage of every individual's reluctance to be cheated. Here again, however, government participation and occasional, well-chosen intervention are absolutely essential elements in this program.

Extensive Self-Regulation Means Less Government Regulation

A review of these and other examples too numerous to mention here shows that self-regulation is more than merely a voluntary compliance with minimum legal requirements, important though this is. These illustrations have covered inspection, process control, sanitation, establishment of standards of good manufacturing practice, analytical method development, and labeling standards. It would seem that self-regulation is more extensive and advanced than most of us realize.

It should also be clear that effective self-regulation in the food industry, and the basic task of consumer protection, of which self-regulation is a part, are best promoted by a certain optimum level of enforcement activity. Above this optimum level, however, the need for government regulation diminishes in proportion to the degree of effective self-regulation by industry.

We come to the conclusion that an effective program of government enforcement should be designed to encourage maximum self-regulation. This will necessarily involve maximizing the advantages to each individual company of effective self-regulation. Such a program can help to free government agencies at every level for concentration upon more pressing and significant problems.

Proposed Voluntary Program of Self-Evaluation

I would like to suggest that it would be appropriate for the FDA, perhaps joined by other related agencies, to meet with qualified industry representatives, through some appropriate organizations such as The Food Law Institute and the Institute of Food Technologists. The objective would be the development of a voluntary program of self-evaluation, limited at least in the beginning, to the areas of plant sanitation and weight control. Many concerns already have extensive and fully satisfactory programs in this field now. There seems no good reason why the FDA should not make use of these programs as an extension and partial replacement of its own. If industry and the Administration could agree upon inspection criteria and reporting

formats, and if periodic reports at reasonable frequencies could be supplied on a voluntary basis by cooperating firms to local food and drug offices, there would seem to be no strong reason why the FDA could not use such cooperation, spot-checked on suitable occasions by its own inspectors, not only as a valid inspection of the cooperating plants but as a basis for more effective assignment of its own personnel. It is now true, of course that the FDA, like most regulatory agencies, tries to concentrate where the need is greatest. Yet it must make routine inspections, even in areas where it knows that little purpose is likely to be served.

Benefits Derived by Industry

It would be necessary to demonstrate to the companies involved that they would not be accepting undue risks in making honest and complete reports, and that, in fact, certain advantages would accrue. First, they would have to be assured that a candid report of a problem and of adequate measures taken to correct it would not be the basis of enforcement action. Second, let us recognize that the FDA historically exercises considerable discretion in deciding whether circumstances justify enforcement action or not. If the Administration were to have positive knowledge that a company, cooperating in such a voluntary program, is in fact conscientiously exercising adequate controls, one could reasonably expect that the FDA would be much less likely to institute a seizure in circumstances where the seizure, however justified in the instance, does not represent a continuous or serious defect in product or process.

Obviously the FDA could provide no advance guarantees on this second point. But let us admit that present procedures following many a seizure have no result other than to reassure the FDA that adequate precautions have been, are being, and will be taken, and that the incident itself was an inexplicable and unfortunate departure from the norm. If this assurance had already been given, on a prior rather than post-seizure basis, the same latitude of decision now available to the Administration could be more knowledgeably exercised, and in many instances, this would avoid considerable trouble and embarrassment. The real concern with which many companies view unfavorable publicity could be a powerful incentive to cooperate.

This is not to suggest that FDA abdicate in any way its responsibilities or its mission. It does propose a new procedure by which the

FDA could employ the discretion it already has to elicit a valuable, further degree of support from any participation by industry in the fulfillment of that mission. An exploration of this line of reasoning might reveal the possibility of a valuable extension of what are already broad and useful programs of self-regulation. **[The End]**

NEW METHOD DEVELOPED FOR DETECTING STAPHYLOCOCCAL POISONING IN FOOD

The Food and Drug Administration has announced a new means of detecting staphylococcal poisoning in food. The agency said it is a major step forward and will for the first time permit the identification in food of the specific staphylococcal toxin which is responsible for most of the food poisoning outbreaks in the United States.

The method, developed over the past 15 years, will save health officials from dependence upon often vague epidemiological evidence during food poisoning outbreaks and the use of expensive animals in tests which are often unreliable. FDA said the method is scientifically accurate and will ease the job of tracking down the sources of food poisoning.

It was reported by Ezra P. Casman, Ph. D., and Reginald W. Bennett, M.S., of FDA's Division of Microbiology, to the 91st annual meeting of the American Public Health Association at Kansas City, Missouri, Wednesday, November 13, 1963.

The new test employs a serological method. Minute quantities of staphylococcal poison in food are detected through use of its antibody, a neutralizing agent developed in the blood of an infected animal.

Food poisoning caused by the staphylococci toxin is generally not fatal to the normal, healthy individual. It may last for only several hours, but is extremely uncomfortable and incapacitating. It is different from the seldom found but often fatal type of food poisoning caused by various botulinus organisms which produce toxins when oxygen is lacking.

FDA's research for a reliable method of detecting the causes of food poisoning began in 1947 with a long-range program which only recently has been completed.

The agency's scientists first demonstrated that nearly all food poisoning cases result from type A toxin produced by staphylococci bacteria. Once this was done, FDA scientists applied a method known as the "gel double diffusion test" to detect and identify the poison. Minute quantities can be detected. The food sample being examined is placed in an electric blender and turned into a uniform mash. A special column—a glass tube containing certain chemicals—is used to separate the toxin from the food parts. The toxin is then removed from the chemical and concentrated.

Samples of the toxin and of an antitoxin are applied to a gel medium into which they are diffused. When they meet a line is formed. The characteristics of this line matched against a known reference line enable the bacteriologist to make a positive identification.

Self-Regulation in the Drug Industry

By ROBERT P. PARKER

Dr. Parker Is General Manager, Lederle Laboratories Division, American Cyanamid Company.

SELF-REGULATION in the prescription drug industry reminds me somewhat of the acrobat who performs a high wire act. Who better could "regulate" his performance than the acrobat himself?

There are dangers inherent in the public activity he has undertaken. His self-interest must be concerned both with the continuing excellence of his performance, as well as avoidance of errors which can too easily have grave consequence while he crosses a myriad of untried open spaces subject to sometimes unpredictable winds and other vagaries.

While this analogy may be a bit far-fetched, it does illustrate, to some extent, the way I view self-regulation in the ethical drug industry.

Because our industry is so inextricably linked with the public interest, we long ago recognized the logic of voluntary imposition of high standards and rigidly controlled procedures throughout all our operations to protect our own self-interest or to ensure that we do not place ourselves in jeopardy. Stated simply, we had to be responsive to the public interest in our own self-interest.

As a member and representative of the ethical drug industry, I must confess that I had not, in the past, given too much serious *analytical* consideration to what self-regulation is and what it really means. Now, having thought considerably about it, I find that the reason for not doing so previously is that *we have been living it, and have been very busy doing just that.*

Much of this effort has been and is being carried on in the everyday aspects of individual businesses and continues unheralded, if not entirely unnoticed. In still many other instances, the industry or

some of its members have combined their efforts in the voluntary responsiveness to the public interest. The record speaks for itself. I cannot, of course, in a short time give a comprehensive run-down on the entire record, nor would I want to. But, I would like to cite just a few cases which exemplify the spirit and substance of self-regulation in action.

Biological Section

As far back as 1917, the American Drug Manufacturers Association, one of the predecessors of the present Pharmaceutical Manufacturers Association, was requested by a group of individuals representing the biological producers of this country "to provide for the creation of a Biological Section of the Association whose province would be to consider those subjects of particular interest to biological producers."

Recognizing the potential public good that could come from such an interested group, the Executive Committee lost no time in recommending an amendment to the ADMA Constitution establishing the Biological Section with the objectives "to promote the welfare of its members" and "to adopt rules and create committees to facilitate its work . . . in the progress made in biological research . . . and the production of biological products." Specifically, the section had in mind and did establish prompt working relations with the Hygienic Laboratory of the United States Public Health Service (later to become the Division of Biologics Standards of the National Institutes of Health) in the field of safety, potency, and various other types of control tests for biological products. Their cooperative efforts have resulted, during the years, in the derivation of many new and improved standards and test procedures for such products. Their work not only continues, but has expanded in cooperative studies with the DBS and with the Committees of Revision of the *United States Pharmacopoeia* and the *National Formulary*.

Of one thing you here today can be sure—the actions of this group of biological manufacturers in 1917 were not triggered by concern over what some senator might say next Friday in Washington!

Combined Pharmaceutical Contact Committee

Another example dates back to early in 1924, when Dr. George W. Hoover, then chief of the Division of Drug Control, United States Bureau of Chemistry (later to become the Food and Drug Administration), posed this question to the drug industry:

> What variations from the declared standards of strength should be permitted in pharmaceutical products?

The industry once again proved that recognition of a problem was all the stimulus needed. Promptly, both the American Pharmaceutical Manufacturers Association and the ADMA appointed working contact committees "to improve the industry's products." By midyear, they had joined forces in a Combined Pharmaceutical Contact Committee and were working together with Dr. Hoover and his staff "in the development of standards and methods of assay for medicinal preparations for which no specific standards existed in either the United States Pharmacopoeia or National Formulary."

Did these men stop to think about self-regulation? Probably not—they *were* living it, however. And once again, it bore public fruit. The result of their efforts is evident in today's *United States Pharmacopoeia.* In 1926, USP X contained only one tablet with a method of assay and tolerances for the active ingredient. By 1947, however, USP XIII had already expanded to contain 64 tablet monographs. In addition to broadening its efforts to include studies on assays and tolerances for parenteral products, the combined contact committee also influenced greatly decisions and actions by the USP and NF to issue formal revisions at five-year intervals and interim revisions even more frequently, rather than at previous ten-year periods. (The five-year cycle began with USP XII which became official on November 1, 1942.)

In view of this group's ever growing responsibility and activities, and its assumption of the over-all aspects of control of quality, it was perfectly fitting in 1962 that the PMA redesignated the contact committee as the Quality Control Section.

Previously, in 1959, the group had already begun work on the document subsequently approved by the PMA Board of Directors entitled "General Principles of Control of Quality in the Drug Industry." This document is genuinely reflective of the character and integrity of the ethical drug industry. An excerpt from its lead paragraph tells the story:

> Control of quality . . . is the organized effort . . . to provide and maintain in the final product the desired features, properties and characteristics of identity, purity, uniformity, potency, and stability within established levels so that all merchandise shall meet professional requirements, legal standards, and also such additional standards as the management of a firm may adopt.

Production

I must admit, ladies and gentlemen, that I have striven to use some self-regulation in keeping these comments within a short time period.

There are so many excellent examples of the drug industry's efforts in self-regulation that chapter and verse could be cited all through the day. However, a very short recitation would be misleading without strong emphasis on our activities in the production field.

We all know what a "quality drug" is—one meeting the highest standards of identity, purity, potency, uniformity and stability. But laws do not put these properties into drugs. The FDA, the USP, the NF and even our quality control people cannot put or test these properties into our drugs. They have to be *built* into the manufacture of quality drugs in the first place. Our research and development laboratories must first devise the pertinent tests and establish the specifications or standards. And then it is our production people who have to devise the rigid operating procedures which enable the quality drug with these standards to be uniformly produced. Over these operations, of course, we spread the vital quality control umbrella for the purpose of auditing raw materials, procedures and products, and guarding against human failure.

It is not at all surprising, therefore, to find that our industry gave encouragement to the establishment of a Production and Engineering Section of the ADMA. This group—set up some 20 years ago, mind you—was to give its attention "to the clarification and resolution of production, engineering, maintenance, housekeeping, packaging, records, plant safety and allied problems." In other words, to bring about an understanding of and compliance with "good manufacturing practices."

This group continues to perform its functions well. Recent contributions which are benefiting the public and the industry include cooperative studies and conferences on in-process quality control; use of electronic data processing equipment in drug manufacturing; design of buildings for control of quality; proper design of production equipment; proper maintenance of equipment; control of containers, labels and cartons; use of plastic containers; training of production personnel; and the like.

Safety and Effectiveness

In making the decision to finance its research privately and not be dependent on federal supported programs, our drug industry has accepted both the challenge and the responsibility to contribute to medical advances through this research. In doing so, we recognized and accepted the obligation to establish as firmly as possible—first in the laboratory and then in the clinic—the desired primary effect of drugs,

particularly new drugs, in animals and patients relative to undesired side or toxic effects.

The acceptance of this responsibility is in a very real sense "a priori" and must substantively precede the establishment of, or reliance upon, legalistic measures. Our interests—both selfish and public—make this so. We are not dealing with mere "chemical entities." We are actually concerned with compositions which are intended to produce a therapeutic or prophylactic effect within a human being. It might well be that ordinary carpet tacks contain the proper elements to correct a certain kind of anemia. But what physician would prescribe six carpet tacks twice daily?

My point here, of course, is that the nature of our business compels us to take exceptional "self-regulating" actions, particularly in the areas of safety and effectiveness.

Therefore, it is again not surprising that some 16 years ago this voluntary character of the industry manifested itself once more. The case in point was the establishment of the Research and Development Section of the ADMA. Simply stated, its aims were "to enhance the research and development activities and programs of the member firms by fostering the mutual encouragement and stimulation of research . . . and to promote cooperative action with outside institutions and organizations . . . ."

This forward action of the industry back in the 1940's, demonstrated its concern with and attention to matters of public welfare initiated without particular regard to the "impact on is public image."

Among many of the very valuable projects of this Research and Development Section was the establishment in 1957 (well before the thalidomide disaster) of a Drug Safety Evaluation Committee. This unit, as you know, after many careful studies, published a particularly useful reference report on the "principles of drug safety evaluation or testing in animals."

This preoccupation of the member firms in the matter of improving our methodology and technology in drug testing was further revealed in 1962 when the Board of Directors of the PMA requested Dr. Lowell T. Coggeshall, Vice President of the University of Chicago, to serve as chairman of an independent Commission on Drug Safety. The objective of the unit was "to broaden scientific knowledge regarding the predictability of action of potent new drugs in humans and to provide coordination and guidance for the professional and scientific

community." The PMA provided the financial support for the Commission which accepted a difficult assignment and discharged it well. Its final report of more than 200 pages issued this past August speaks for itself.

I have not discussed the work of the Medical Section of the PMA, for instance, which involves itself with such problems as clinical drug evaluation, training of clinical investigators, poison control, narcotic drugs, and so many other activities.

Now, in spite of all of the foregoing, please do not conclude that I believe the industry "has wings and lives on a cloud." Neither does it have a "forked tail." I have tried to show merely that it has demonstrated character, integrity and ethical behaviour.

Why, then, must there be government controls? I, for one, regard government control, if it does not involve over-control, as a necessary additional "audit" in the public interest. The drug industry, as the high wire performer, works in an area where risk is a continuing fact of life. We must do all we can to reduce this risk wherever we can. In this regard, the government fulfills an important role as long as its activities are conducted in an open and positive manner. Progress and initiative must be encouraged, not stifled. The examples of such cooperative efforts which I have cited have proven to be valid, meaningful and useful.

Further, we do not view the industry's aspects of self-regulation as complete alternatives or substitutes for government regulation. The two are not mutually exclusive, but are and must remain complementary.

Outlook for the Future

The future? Well, it seems quite clear. Science and technology are dynamic, and our industry is built on our scientific and technological advances. As a consequence, we will continue to face changes and new problems which will demand a continuing, if not stricter, internal regulation.

New potent drug discoveries, new methods of production, new instrumentation, new assay techniques, new methodology in clinical sciences, new methods of scientific communication—these are but a few of the problems with which the cooperative efforts of the industry, the medical and pharmacy professions, and the federal and state regulatory agencies must cope and resolve.

Conclusion

If I may take some liberties with a pertinent section of a recent report of the United States Department of Commerce entitled, "Self-Regulation in Advertising," I would like to conclude with the observation that our industry has developed and will continue to improve its organization, its machinery and procedures to

(1) Encourage the development of standards higher than those imposed by law;

(2) Contribute to the self-imposition of higher standards under law itself; and

(3) Promote obedience to law itself.

My deep-seated belief in the freedom of the individual can be consonant only with the true spirit of self-regulation. I believe the public interest will be served well because of the industry's character, as it has been in the past. **[The End]**

LACK OF MANUFACTURER'S INSTRUCTIONS FOR USE NO BAR TO SALE OF PRODUCT

Charges and affidavits by a manufacturer that his cartons of hair color bath, packaged, labeled and sold only for professional use, were being broken up into individual containers for retail sale without the original instructions for use prepared by the manufacturer for its single bottle retail package, were not sufficient to warrant a temporary injunction prohibiting such retail sales, the New York Supreme Court in New York City has held.

The manufacturer pointed out that cartons prepared for sale for professional use do not contain instructions for the use of the product by the general consuming public. Without these instructions as a safeguard, the manufacturer contended that users may be injured with the concomitant deleterious effect upon the manufacturer's reputation.

The court rejected the manufacturer's contention, as a basis for terminating the sales, that the users of the product might be injured. The court noted that the retailer had averred that instructions for use were supplied by his shop to each customer. These instructions, the court found, were virtually identical to those in a prior case involving the same product but a different retailer, in which, after trial, injunctive relief was denied. However, the court did order that the instructions prepared by the retailer be furnished with each sale.—*Clairol v. Doe* (NY Sup. Ct. 1964), FOOD DRUG COSMETIC LAW REPORTS ¶ 40,158.

Science Promotes Voluntary Compliance— The Nonmedical Viewpoint

By O. L. KLINE

Dr. Kline Is Assistant Commissioner for Science Resources, Food and Drug Administration.

IN THE TITLE "Science Promotes Voluntary Compliance," I take the word "science" to refer to scientists as a group of people in the Food and Drug Administration and in industry who have an opportunity to educate each other in developing the best possible understanding of the law, the regulations, and the kinds of information that must be utilized in our regulatory process. It is trite to say that science has provided a universal language. Trite or not, it is true that in the area of scientific matters, we do have a means for developing understanding that is essential to meet complex requirements in the development of adequate data for safety and usefulness. In my discussion, I propose to treat particularly the nonmedical science component of the subject, leaving to my colleague, Dr. Pisani, the medical aspects.

In the FDA, my former chief, Dr. E. M. Nelson, whom many of you remember with affection, was a strong proponent of voluntary compliance through full understanding of the scientific aspects of our regulatory function. I can testify that throughout the more than 25 years that I was associated with Dr. Nelson, he devoted his full energies to the development of an increased comprehension of the scientific bases and experimentation that underlie the regulations established under the Food, Drug, and Cosmetic Act. It was through his open-door policy, with many and frequent visits from scientific colleagues in industry, that he was effective in developing a high incidence of voluntary compliance in the nutrition and special dietary food field with which he was directly concerned.

We have come to give even greater emphasis to this need for better understanding as a basis for voluntary compliance, as evidenced,

for example, in our efforts that followed the passage of the 1958 Food Additive Amendment. There was much concern on the part of industry scientists as to the methodology to be used in developing data that would adequately demonstrate the safety of one or another chemical substance classified as a food additive. Our pharmacologists and food chemists were called upon almost daily to meet with industry scientists and to work out together the best protocol for tests that would accomplish the desired purpose. I am sure many of you played some part in this industry-FDA scientific relationship. The standards for safety testing and safety evaluation which were worked out reflect the cooperative spirit and the desire to meet the requirements of the new law as effectively as possible.

FDA's Research Program

In addition to exchanges of information that occurred in the many meetings and interviews that related not only to the food additive problems, but to pesticide residues, discussions in the fields of nutrition, microbiology and drug chemistry, we have developed other scientific relationships that aid in voluntary compliance. Our scientific research program has established for us a firm place in the scientific community. Through exchanges of information by our scientists in attendance at society meetings, in their capacities as members of committees, boards and associations, in their contributions to the literature and review of the literature, we have created an atmosphere in which there is mutual respect and understanding between industry and FDA. I would like to review briefly the highlights of our research program. It makes an exciting and impressive story to outline the areas of research in which our FDA scientists are engaged and to point out the significant findings that have established important new developments in methodology and new concepts in a number of scientific areas. I shall take time to call attention only to two or three examples of recent research developments that we regard as of significance.

Our studies cover the areas of pharmacology, nutrition, food chemistry, pharmaceutical chemistry, color and cosmetic chemistry, and microbiology. Important advances have been made in the development of knowledge about the enterotoxin produced by food poison staphylococci. We can now extract, concentrate, and identify the minute amounts of enterotoxins present in foods involved in outbreaks of food poisoning. Using the procedures by which this information was developed, we shall expand to a broader study of the distribution of enterotoxin-

producing organisms in foods. Much new information has been developed on the botulinus type E organism, the conditions under which it is controlled, and particularly, by electrophoretic means, identification of the degree of heating to which smoked fish may have been subjected by measuring changes in the protein fraction. This provides a regulatory test of some importance.

New Methods of Detecting Pesticide Residues

Our methodology for the chlorinated pesticide residues has developed to the point that we have useful and effective screening procedures which allow us in a single determination to detect and determine the identity of the pesticide residues on a shipment of food of unknown history. We have not had this capability with respect to the organophosphate pesticides. A recent invention by one of our chemists of a new type detector for the gas chromatographic system increases the sensitivity several hundred times to give us a differentiation of the phosphates which has not before been possible. Parallel with this development is a discovery by a laboratory outside the FDA working with us under contract which provides another type of detector for the gas chromatographic system. Application of these new instrumental developments will increase our effectiveness in measuring the pesticide residues present on interstate shipments of raw agricultural food commodities.

Use of Infrared Absorption

The use of infrared absorption provides an important means of identifying unknown chemical constituents of foods, drugs or cosmetics. We have created a reference library of infrared absorption curves, each of which is specific for the compound measured. This library has now become a part of the National Bureau of Standards, Office of National Standard Reference Data. This is available to any chemist who wishes to make a comparison with a series of standard curves of known compounds.

The use of infrared absorption requires that the substance under examination be dissolved in a suitable solvent. It has been found in our laboratory that infrared aspects of opaque substances, such as coatings on food packaging materials, can be obtained by newly developed reflectance techniques. The attenuated reflectance infrared spectra of the surface of 23 different co-polymers have been recorded. This system should be most useful in identifying various films and packaging materials. This is an important extension of the use of infrared.

Our chemists have found that by X-ray fluorescence they can identify heavy metals in batches of colors offered for certification and also in a variety of cosmetic preparations. Presumably, this technique may be applied to a variety of sample materials. This is quite sensitive and will identify very small amounts of substances that may be undesirable.

With the finest cooperation with other government agencies, with interested members of the food industry, and with academic institutions, we have with considerable speed resolved a number of the problems related to mycotoxins and specifically aflatoxin which has been identified as a contaminant in certain peanut products. We now have effective and rapid biological assay techniques and a chemical procedure which is sensitive to less than 1 p.p.b. of this substance. With such analytical tools, we have been able to develop a regulatory program that gives assurance that our food supplies can be prepared uncontaminated with this toxic substance.

It is with considerable pride that we point to an increase in our scientific staff which has provided research capacity in some depth to carry out our mission. The principal assignment of our bureau of Scientific Research is one of basic research projects which occupies the attention of approximately 300 professional people. In the Bureau of Scientific Standards and Evaluation, which carries the function of review of petitions and applications, there is additional research capacity in the more than 225 scientists that are assigned to this bureau. Seven hundred chemists and related scientists occupy the laboratories of our 18 field districts, where we have not only the day-to-day analytical program, but a significant assignment of research, particularly in the field of development and validation of methods carried on by that group.

Recognizing the need for continued refreshing of our scientists, we have developed, in cooperation with Georgetown University here in Washington, the Institute for Advanced Analytical Chemistry. By the end of this year, we will have graduated more than 100 of our chemists, each of whom has spent an intensive three months in the study of a variety of instruments which have now become an integral part of our program of sample analysis. The liquid gas chromatography system is essential in our pesticide residue analysis, in our research on fats, and in a number of other such areas where separation by this means can be accomplished. The nuclear magnetic resonance has become an important system for identifying unknowns. Polarography

plays its role in our analytical program. X-ray fluorescence and photofluorometry have become of routine use. The Georgetown Institute has provided a means of developing proficiency through understanding of the theory, mechanics, and the application of these analytical tools. This is a pattern of teaching that could be carried to other parts of the country wherever there are operating chemists who need the opportunity for review of the advancing science and an opportunity to work in an academic relationship to understand the new instrumentation and the new methodology, particularly in the analytical field.

We are developing a program of exchange of scientists with academic centers in the hope that outstanding investigators may wish to join us and work in our laboratories for their sabbatical period. This will provide stimulation to our staff, new ideas and research accomplishments on subjects that are of mutual interest.

Of great concern in recent years has been the matter of handling and dealing with the large mass of information that the scientists must evaluate and absorb. This problem is of significance, not only in the nonmedical science subject area, but also in dealing with medical information that relates to the use and safety of drugs. Expert advice has been sought as to the best method for coordinating and handling the science information in the FDA. The Arthur D. Little firm of consultants has provided a feasibility study and is now in the second phase of development of a system which, in brief, is made up of a central retrieval index with its related satellite files containing information in terms of all chemical compounds with which we must deal in the FDA. The establishment of this central retrieval index into a computerized form rests upon the ability to code chemical compounds in terms of computer language. In our Bureau of Medicine, an IBM punch card system has been developed to handle the great volume of drug information. This experience has been helpful in further adaptation to computer use. The continued development of our information system, of course, depends not only on our ability to automate the handling of information, but to educate the contributors and the users of the system. Better coordination and availability of information will be of benefit to our industry and academic colleagues.

With our increasing capability in developing research, with our more effective handling of science information, and with our continuing cooperation with industry scientists in meeting and understanding the complex scientific problems of the day, we can say with assurance that science truly promotes voluntary compliance. **[The End]**

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