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Food Drug Cosmetic Law JOURNAL

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

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

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REPORTS

TO THE READER

Compliance with Drug Abuse Control Amendments of 1965.—In this article, beginning on page 360, *Harold F. O'Keefe,* Director of the Division of Industry Advice of the Food and Drug Administration, discusses the 1965 amendments. Three groups of drugs are covered by the law, whether or not these drugs are moved across state lines. Drugs covered by the law are those which contain habit-forming barbiturates, those which contain amphetamines, and additional drugs that the Secretary of Health, Education and Welfare (HEW) designates. Mr. O'Keefe points out that all drugs controlled under the amendments have legitimate uses; the bill is aimed at the abuses, while permitting legitimate traffic. New powers are provided for officers of HEW, and special penalties are provided for peddlers over the age of 18 who supply anyone under 21 with the drugs.

FDA Statement and an Industry Response.—A constructive dialogue between the FDA and the food industry is featured in this issue. Both speeches were delivered at the meeting of the Grocery Manufacturer's Association, Inc. (GMA).

In **"Issues and Some Answers,"** beginning on page 368, *Dr. James L. Goddard,* FDA Commissioner, calls for an effort to keep the consumer informed about new developments in foods. The responsibility of the FDA is expanding as imports and exports increase. The FDA intends to maintain the same standards for food and drug imports and exports as it maintains for products for home consumption. One issue needing immediate attention is the unsanitary conditions of food handling.

In **"What the Food Industry Needs from the FDA,"** beginning on page 373, *C. W. Cook,* President of General Foods, asks that the FDA inform the food industry of what it considers to be the correct practices. The food industry also wants advice and guidance on unclear issues. The FDA should realize that some risks must be taken in order for any progress to be made. Mr. Cook asks that the FDA be aware of and make use of academic and industrial facilities. Industry must share responsibility with the FDA for keeping the public informed, but the food industry has the right to expect a literate and well-informed public.

What the Consumer Expects, and Receives, from the Administration of the Federal Food, Drug and Cosmetic Act.—In this paper, given as the Annual Charles Wesley Dunn Memorial Lecture, and starting on page 377, *Elaine G. McNally,* Consumer Specialist for the Los Angeles District of the United States Food and Drug Administration, calls for increased consumer education, both about the functions of the FDA, and about the products found on the market. Mrs. McNally cites instances from her own experience illustrative of the consumer's desire to learn exactly what is in the products he purchases, and of certain practices of producers which may tend to frustrate this desire. The author concludes that it would be to the benefit of industry to engage in a program designed to inform the consumer.

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Food·Drug·Cosmetic Law
Journal

Compliance with Drug Abuse Control Amendments of 1965

By HAROLD F. O'KEEFE

The Following Article Was Presented at the Seminar of the Food Law Institute, Inc., at the School of Law, Northwestern University, Chicago, Illinois, on January 28, 1966. Mr. O'Keefe Is the Director, Division of Industry Advice, Bureau of Education and Voluntary Compliance, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D. C.

THE DRUG ABUSE CONTROL AMENDMENTS OF 1965 are liked by all public-spirited citizens; the Congress voted for it almost unanimously; the pharmaceutical industry, both manufacturers and pharmacy representatives, voiced general approval before the Congressional committees even though some suggested changes of certain sections; the representatives of consumers strongly advocated it; and the executive branch of the federal government urged its passage. President Johnson personally endorsed the November 1963 recommendation of the President's Advisory Commission on Narcotic and Drug Abuse that all nonnarcotic drugs capable of producing serious psychotoxic effects when abused be brought under strict control by federal statute.

Immediately following signing of the law, steps were taken to promulgate regulations implementing its requirements. Also, in accordance with the intent of Congress, a scientific advisory committee was appointed by the Secretary of Health, Education and Welfare (HEW) to consider which drugs other than barbiturates and amphetamines should be brought under control.

Because illicit traffic in the regulated drugs interferes with and depresses legitimate interstate traffic, the law applies to the drugs whether or not they have moved across state lines.

Drugs Covered

Three groups of depressant or stimulant drugs are covered by the law. These are:

1. Any drug that contains a barbiturate which we have designated as habit forming. In regulations that have been in effect some years we have designated the various barbiturates now used in medicine as habit forming, as well as their salts. Thus, these compounds are automatically subject to the law. Barbituric acid and its salts are also covered.

2. Any drug that contains amphetamine or any of its optical isomers or any salts of these compounds. Thus, the amphetamines are now covered.

3. Additional drugs that the Secretary brings under coverage of the law by regulation. These may be drugs containing:

a. Any substance which the Secretary designates as habit forming because of its stimulant effect on the central nervous system.

b. A substance which the Secretary designates as having a potential for abuse because of its depressant or stimulant effect on the central nervous system or because of its hallucinatory effect. The legislative history of this provision shows that the Congress intended for products in this category to have a potential for more than isolated abuse.

Certain drugs will be exempted from the provisions of the amendments. These are:

1. All drugs that may lawfully be sold without prescription.

2. Combinations of depressant or stimulant drugs *with other drugs* where the Secretary finds that the combination does not have the effect at which the bill is aimed.

3. Depressant or stimulant drugs whose regulation the Secretary finds is not necessary for protection of the public health.

Almost without exception, all drugs controlled under this amendment have useful and legitimate uses. However, they are being abused and this abuse is one of the major health and social problems in America today. It is made possible by the diversion of dangerous and habit-forming drugs from legitimate medical uses to nonmedical uses, and from legitimate professional channels into illegal channels. It has been estimated that over nine billion barbiturate and amphetamine capsules and tablets are manufactured annually in the United

States, and that about half of them are sold illegally. Diversion to nonmedical use is contributing to the rising death toll on the highways, juvenile delinquency, violent and bizarre crimes, suicides, and other antisocial behavior.

Illegal traffic in such drugs is enormously profitable and has attracted organized criminals. Amphetamines, or "bennies," which can be purchased at wholesale for about $1.00 per thousand, are often sold to a middleman illegally for about $30 to $50 per thousand, and then peddled at retail for as much as ten cents to 25 cents a pill—equal to $100 to $250 per thousand. The illegal profit in barbiturates is even larger. We have uncovered organized rings that have been bootlegging barbiturates and amphetamines on a very large scale running into the millions of pills and covering several states.

Obviously, somewhere along the regular lines of distribution, these drugs are being diverted from legal medical use to illicit nonmedical use. These diversions can occur at any point in the chain of distribution. We have found diversion of the basic chemicals, diversion at the manufacturing end, diversion at the wholesale and retail levels, and diversion through physicians and retail pharmacists. Rarely, however, have we found any significant diversion by a responsible individual such as a pharmaceutical sales representative.

The new law is designed to eliminate illicit traffic in depressant or stimulant drugs while permitting legitimate traffic among bona fide manufacturers, wholesalers, pharmacists, and users who obtain the products on a prescription. Certain other persons who may properly possess the drugs are named in the statute. They include such groups as doctors, nurses, and government agents engaged in the legitimate practice of their professions.

Record Requirements

The amendments prescribe a system of record keeping that is designed to permit government agents to audit the movement of depressant or stimulant drugs from the time they are produced until they reach the consumer. Every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of psychotoxic drugs must prepare an initial inventory of stocks on hand as of the effective date, February 1, 1966, and thereafter keep accurate and complete records showing quantities manufactured or received and their disposition. These records must be maintained for a period of three years and must be made available for inspection by authorized agents of the Administration. Thus, the agents will

be able to detect points of diversion of the drugs to illicit channels, and to institute corrective measures where necessary. These record keeping requirements apply to physicians' samples which may be given out by pharmaceutical sales representatives.

Those who manufacture, wholesale, or job stimulant and depressant drugs must register with the Food and Drug Administration (FDA).

The following acts are specifically prohibited by the new amendments:

1. Manufacturing, processing, or compounding the designated drugs, except by registered drug firms for legal distribution.
2. Distributing the drugs to any persons who are not authorized by the federal or state law to receive them.
3. Possession of depressant or stimulant drugs except as authorized by law.
4. Refilling of prescriptions for these drugs more than five times or more than six months after they are initially prescribed.
5. Failure to prepare, obtain, or keep the required records and to permit inspection and copying of such records.
6. Refusal to permit entry or inspection as authorized.
7. Making, selling, keeping, or concealing of equipment for counterfeiting drugs, and the doing of any act which causes the sale of a counterfeit drug.

The amendments provide special penalties for peddlers over 18 years of age who sell or give the drugs to anyone under 21 years of age. For a first offense, the punishment may be imprisonment for not more than two years or a fine of not more than $5,000, or both. Subsequent violations may carry a penalty of not more than six years' imprisonment and/or a fine of not more than $15,000, or both. Otherwise, the penalties for violation of the Amendments are the same as other actions under the Federal Food, Drug and Cosmetic Act: $1,000 maximum fine and/or one year imprisonment for a first offense, $10,000 and/or three years for a second offense, and for willful violation. Seized drugs are subject to condemnation and destruction. Injunctions may be issued by the courts to restrain the performance of prohibited acts.

The new law provides authority for officers and employees of HEW, who are designated by the Secretary to conduct examinations or inspections relating to these drugs, to:

1. Carry firearms
2. Execute or serve arrest or search warrants

3. Execute seizures with or without libels of information (subject in the latter case to prompt institution of libel proceedings)

4. Make arrests without warrants in certain cases.

Previously, our agents did not have any of these powers. Specifically what does this all mean? On February 1, 1966, all legal handlers required to maintain records must prepare a complete and accurate inventory of stocks of depressant or stimulant drugs, unless exempted by regulation, on hand as of that date. Thereafter, they must prepare or obtain and keep records covering the receipt and disposition of all drugs covered by the law unless specifically exempted. These records must include:

a. the kind and quantity of each drug

b. the name, address, and registration number, if any, of the person from whom the drug was received or to whom it was delivered, and

c. the date of the transaction.

These records need not be kept separate and apart from the regular records as long as they are readily available for inspection by Food and Drug investigators. Of course, separate files on these depressant and stimulant drugs may be maintained if so desired. These requirements are applicable to manufacturers, wholesalers, distributors, jobbers and their representatives, pharmacists, and to physicians and other licensed practitioners who regularly engage in dispensing stimulant or depressant drugs to their patients and who make a charge for the drugs either separately or together with charges for other professional services.

These records we have been talking about must be kept for a period of three years and made available to FDA inspectors at reasonable times on request.

To comply with the record requirements, prescription orders must include the name and address of the patient and the issuing date which normally appear on all prescription orders. Stimulant or depressant drugs may be dispensed on written or oral (such as telephone) instructions of the physician. Of course, the oral instructions must be reduced promptly to writing by the pharmacist. As I outlined earlier, under the amendments, no prescription for a stimulant or depressant drug may be filled or refilled more than six months after the date of issue. Also, no such prescription which is authorized to be refilled can be refilled more than five times. However, after the five refills or six months, the prescription may be renewed by

the physician issuing it either in writing or orally (if promptly reduced to writing by the pharmacist). These requirements apply to all prescriptions for these drugs after the law becomes effective, regardless of the date on which they were written.

Were I to conclude my talk with you at this point, I am most certain that the first question "thrown" at me by many of you would be—"Just exactly what drugs are covered by this law?—Which drugs must we inventory and keep records of?" I can only give you a partial answer at this time. The law specifically requires an inventory on February 1, 1966, and record keeping thereafter of all drugs containing barbiturates or amphetamines, except those which may be sold without prescription, and which are exempted by regulation. It provides for inclusion of other drugs that have a potential for more than isolated abuse, and for the Secretary to exempt by regulation combinations of depressant or stimulant drugs with other drugs or depressant or stimulant drugs by themselves which do not have potential for abuse and for which such control is not necessary for protection of the public health. I can tell you that we have been working feverishly in the preparation of proposed procedural regulations, some of which have appeared in the *Federal Register* very recently.

Published Regulations

Let me quickly list the regulations which have been published in the *Federal Register* to date:

September 17, 1965—Registration regulations revised to include wholesalers, jobbers, and distributors of any depressant, stimulant, or hallucinogenic drug.

November 3, 1965—Procedural regulations for setting up advisory committees for consideration of "abuse" drugs.

December 18, 1965—Proposed regulations spelling out the definitions of the terms used, the drugs covered, persons covered by the record keeping requirements, types of records to be kept, etc., and interpretation of the requirements and procedures generally.

December 18, 1965—Invitation for submission by industry of drugs containing depressants, stimulants, and hallucinogenics which should be exempted from control.

Also invited were views as to whether a distinctive product-identification symbol should be required on the label of any controlled drug.

December 29, 1965—A revision of the definition of the terms "wholesaling, jobbing, and distributing" in the registration regulations so as to exempt from the need for registration pharmacies whose sole reason for registration was delivery of abuse drugs to a practitioner (except for a dispensing practitioner), or to other pharmacies to meet a temporary inventory shortage.

January 8, 1966—Postponement of the record keeping requirements until August 1, 1966, for (a) depressant or stimulant drugs which may be lawfully sold over-the-counter without prescription, and (b) drugs containing amphetamines or barbiturates combined with other drugs. This does not apply to amphetamines or barbiturates by themselves or combined only with each other.

January 18, 1966—Proposed regulations to include control of seventeen additional drugs having a potential for abuse.

Thus, as you can see, we have been and are moving as expeditiously as possible to implement the requirements of the Amendments, consistent with adequate consideration and study and the procedural requirements pertaining to promulgation of regulations.

Summary

In summary—as of today

(A) Producers of and distributors (including pharmacists and regularly dispensing practitioners) must, on February 1, take an inventory of the following drugs: (1) amphetamines, (2) barbiturates, and (3) combinations of these two drugs with each other, and must maintain records of all receipts and dispositions of all such drugs thereafter

(B) All producers and distributors of "abuse" drugs (as defined in the act and regulations) must be registered with us, beginning February 1

(C) Unless the effective date is further postponed, all OTC and combination drugs not exempted by regulation will be covered by these same requirements as of August 1, 1966.

The effective dates for any additional drugs brought under control will be designated in the final regulations as issued.

We will be glad to add your firm's name to our mailing list to receive a copy of the proposed and final regulations as issued if you will write to the Food and Drug Administration, Division of Industry Advice, Washington, D. C. 20204.

I would like to add at this time that we are always ready to do all within our means to encourage voluntary compliance with the requirements of the Federal Food, Drug and Cosmetic Act and the other acts which we administer. By voluntary compliance we mean, of course, not indulgence in wrongdoing after the fact but rather taking steps to prevent the violation before it occurs. We are always glad to offer the benefit of our thinking with respect to interpretation of the acts we administer and the application of their requirements to any specific product or products if you will send us the full details. Such inquiries should be sent to the above address.

Our goals over the next several years are to achieve rapid yet measured program expansion to substantially curtail the illicit traffic in stimulant and depressant drugs, and to deal promptly with counterfeit drug problems as they arise. We expect to give major attention to the conduct of educational and research programs as well as enforcement operations. Obviously, we will need, and we solicit, the cooperation of state and local enforcement officials and industry. We would like to turn over to the states the primary responsibility for control of those phases of the psychotoxic drug problems which are most amenable to state control where the states have the manpower, the law, the funds, and the willingness to undertake a significant share of the enforcement load. We are already developing through the National Association of Boards of Pharmacy and Association of Food and Drug Officials of the United States a pilot program designed to give selected states the primary responsibility for regulating traffic in psychotoxic drugs through pharmacies and certain other legitimate channels. The response of these Associations to our preliminary discussions has been most gratifying. Just as important and necessary is your aid in combating the vicious practice of illegal distribution of psychotoxic drugs and counterfeit drugs prepared under catch-as-catch-can controls, if any, which endanger human lives. You can and should be with us in the front line of attack. Let us know of any suspicious circumstances which you believe bear looking into, whether it be with respect to counterfeit drugs, illegal distribution of psychotoxic drugs, or any other violation pertaining to drugs which may endanger the public health. As professional members of the drug team, you have a definite share in our mutual task. We solicit your help so that our joint efforts will curtail, if not eliminate, the peddling of barbiturates, amphetamines, tranquilizers, counterfeit drugs, and the like, which at the present time is over-shadowing the illicit narcotic traffic. **[The End]**

FDA Statement and an Industry Response

Issues and Some Answers

By DR. JAMES L. GODDARD

This Article Was Presented at the Meeting of Grocery Manufacturers of America, Inc., at White Sulphur Springs, West Virginia, on June 21, 1966. Dr. Goddard Is Commissioner of the Food and Drug Administration.

I KNOW THE FOOD INDUSTRY and the Food and Drug Administration have had good working relationships in the past. My staff has convinced me of this. There has already been ample evidence by many food producers who have visited my office that the willingness of private industry to cooperate with us has not diminished. Nor is it my intention to let anything in our agency erode or otherwise interfere with this relationship.

But I am sure you will not construe this to mean that we see no issues ahead. There *are* issues and we *do* have to contend with them together. I use the term "issues" in a most general sense, however. You might prefer to call them "problems" or "challenges" or "opportunities." With your permission, then, I would like to lay before you some of the issues yet remaining and to suggest some ways we might meet these issues together and resolve them.

Yesterday my staff and I appeared before Representative Paul Rogers, Chairman of the House Special Subcommittee on the Department of Health, Education and Welfare Investigations. I informed Mr. Rogers and his colleagues that we hoped to establish an Office of International Affairs within the Office of the Commissioner of Food and Drugs. We are moving in this direction for an obvious reason. The rate of international traffic in foods is on the rise.

In 1964, the value of food exports ran to 3.946 billion dollars. In 1965, the value rose to 3.968 billion dollars. This increase in the dollar value of food exports from the United States is expected to continue. I might add that the balance of exports over imports is running in our favor.

This international movement of foods is something to ponder. American tastes, as we know, are becoming more and more sophisticated, and the American consumer is becoming more interested in foods of foreign origin. Many companies have taken advantage of this phenomenon, and are now moving aggressively into a broader food import program.

The inspection of food products imported into the United States is among the responsibilities of the Food and Drug Administration. As I indicated, it is a responsibility that has expanding dimensions. In order for our agency—and the industry—to identify problem areas and work out possible solutions *before* actual troubles arise, we must have an organizational unit staffed and equipped right at our headquarters level.

There is, of course, the export side, also. No one questions the extraordinary capacity of the American grower to produce quantities of food far in excess of domestic needs. It has been a mixed blessing, one that challenges the best thinking of the best agronomists in this nation. However, for many other countries, that blessing is not mixed at all. From our farms and from our dairies, from our canneries and our packaging plants, from our vast food industry come the tons of foodstuffs without which many countries would face starvation.

Food and freedom are inseparable, in this nation as in other nations of the world. The family that has its basic nutritional needs satisfied without exhausting its energies in the process is a family that can assume larger social and economic responsibilities. It is a family that will speak for peace, for brotherhood, for the protection of children rather than the exploitation of children. And it has been the policy of the United States for several generations now to make available our abundance to families everywhere.

This policy carries heavy responsibilities, of course. If we are to export American-grown and -packaged foods to other nations, we must be sure that those foods meet the highest standards of safety, cleanliness, and honest labeling we can establish. It is not possible for us to have double standards, either. We do not have a double standard when we seek allies in the worldwide struggle for peace and self-determination. Why, then, have a double standard for food to feed those allies—whether the food is provided as part of a governmental aid program or is sold through private industry's own export efforts?

I find it difficult to accept a double standard in food exports. I would think that *you* must also have the same difficulty. I also believe that the profit available from the export market need not be materially diminished if every company in the export field maintains the same high level of food production and processing as if its goods were destined for home consumption. To help in this matter, our new Office of International Affairs will be established and appropriately staffed.

The "Standard of Identity"

I have mentioned standards here in the most general way. But we know that there is such a thing as a food "standard of identity." It is to this kind of standard that I would like to turn next.

There is no question in my mind that the food industry has made exceptional progress in developing new processing and packaging techniques. You have expanded the food distribution capability of this country in a variety of ways: greater use of containerization, the development of more versatile air, water, and land freight carriers, and new techniques in packaging and shipping perishables. In addition, there is the growing area of convenience foods—frozen foods, ready-to-bake pies and pastries, and other categories. The manufacturing of these foods and the techniques of packaging them cause me some concern. I am not sure that adequate control procedures are always present and used. Nor am I sure that we have made every effort to adequately inform the consumer—nor the intervening product handlers—of what is needed to maintain product integrity.

In other words, I raise this issue with you today: have our laboratories and our marketing agencies outrun our personnel responsible for keeping every element of the food industry—and the consumer, too—properly educated about these new developments? I must pay far more attention to this matter before making any final judgments, but what I have observed thus far leads me to believe that both the industry and the Food and Drug Administration have a distance yet to travel before acquitting ourselves fully of our responsibilities in the area of food standards.

President Lyndon Johnson noted in his Consumer Message to Congress in March: "If the consumer is to be a wise sovereign in our progressive market economy, he must be fully informed." I think we all would agree with that statement, which lies at the heart of our food standards program. In the spirit of that statement, our agency will be moving forward to establish new standards of identity for a

number of food categories—in frozen foods, in baked goods, and in fish, particularly. The food industry should be able to anticipate our actions in this endeavor and come to us with some constructive suggestions for action. Naturally, the final decisions will be ours, but that does not preclude communications between us beforehand. As I indicated earlier, full and open communications between industry and our agency is a basic tenet in my administration.

The establishment of food standards is not an end in itself; it is but one of several means to keep progress moving in the food industry. It needs constant revision, and we are accomplishing that. But it is not the sole answer. Once again I must stress the need to maintain a constant link of communication and information between the originating source of our foods and the consumer. Every person involved in the movement of our food supply must know the significance of his work, in relation to the public health. As the consumer cannot wisely purchase food without adequate information, so the distributor and retailer cannot wisely handle food without full information.

I hope you will not mistake my remarks as being merely a plea for better labeling practices, more standards of identity, better employee training programs, or better advertising. I have all these in mind—but I can think of other practices, too, which together form a total information function, a continuous interweaving of facts among all elements of the food industry, from original producer to final consumer. To view this total function bit by bit or tactic by tactic is no longer adequate for leadership in this industry. I urge each of you to work with your staffs so that a fully informed industry and a fully informed public can keep pace with the technological advances of your laboratories and pilot plants.

Unsanitary Conditions in Food Handling

I began my remarks today by speaking of general issues that deserve our attention for future action. But now let me speak of an immediate issue that must be dealt with immediately. Frankly, I am embarrassed for both of us that I must bring it up at all. Yet, I cannot discuss problems without mentioning the problem of unsanitary conditions in our food handling. You are aware, I am sure, of our seizure blotter. I review it periodically to see what kinds of problems we are meeting in the field. I am also interested to see which companies are causing our agency and the consumer the most problems. So it is with some dismay that I continually see the record of seizures swelling with incidents of rat infestation, insect excreta and webbings, bird filth, fly eggs, and maggots. This kind of problem

should have been resolved decades ago. There is no secret to sanitation; more manuals have been written and published on this one subject alone than possibly on all others in the food field. Then why do we still have to expend so much of *our* manpower and destroy so much of *your* product in seizures because of filth? It is an exasperating condition, one that tries my patience; and I'm sure it must try yours, also.

We will not, of course, allow any of these contaminated and infested cargoes to enter the marketplace. If we have to aggravate the situation by tougher enforcement, I will be greatly disappointed. I hope, instead, that the food industry itself—whether through organizations such as this or simply by a sense of responsibility being exercised within each food establishment—I hope that self-regulation in this area of sanitation will be accomplished.

Monitoring the National Food Supply

As it is, the task of monitoring our food supply nationally is quite extensive. We cannot do the job by ourselves and we make no bald statements to the contrary. The partnership of effort we enjoy with state and local governmental agencies is, therefore, invaluable. We are doing all we can under present authority to strengthen these relationships and make these agencies more effective. President Johnson has proposed further legislation in this area.

The Professional Training and Cooperation Amendments of 1966, now before the Congress, would expand our authority to provide technical assistance to food and drug agencies at the State and local levels of government. This is legislation that will materially help us carry out the provisions of the Federal Food, Drug, and Cosmetic Act without an inordinate degree of increase in the staff and facilities of the Food and Drug Administration itself. On the other hand, it will assist the States in developing their own capabilities, equal to ours and consonant with the needs of public health and service. We are, of course, hopeful that this important piece of legislation will pass the Congress this year. Certainly it would be to the advantage of the food industry—the thousands of individual growers, packers, shippers, processors, distributors, wholesalers, and retailers—to have well-trained personnel in *every* State and local agency. Special problems can then be solved more quickly and just as competently on the spot where they occur.

However, the present rhythm of enforcement will be maintained and, wherever possible, accelerated in this matter of cleanliness and sanitation. It is a fact that instances of salmonellosis in humans are occurring at the rate of over 20,000 a year. I am using a rounded

figure, because isolations of salmonellosis are still grossly underreported. This is an intolerable situation. I know from my experience as Chief of the Communicable Disease Center of the Public Health Service that such a statistic can be reduced, that such a threat to our national well-being can be eliminated. We have the scientific know-how and we have the organizational and administrative know-how. But what we seem to lack is the commitment. I ask you today to make this issue of sanitation an object of full commitment by this Association. And I ask you today to bend every resource in this industry to the eradication of unsanitary conditions and the elimination of food-borne disease micro-organisms, such as salmonellosis, botulinus, and staphylococcus. When the housewife buys your product, she is placing her faith in your ability to contribute to her health and the health of her family. And you have the ability to do this. The fact that we still have a serious issue to face here is not, in my opinion, a reflection on your technical ability. But it is a definite reflection on your lack of full commitment to resolving this issue once and for all.

I feel sure that this will come about. Our agency is working in this direction both in the field and in our laboratories. Our scientific personnel—together with yours—exchange the kind of new data that are contributing to a final resolution. Thus far, the pace has been slow—too slow for the public to tolerate. Let us, then, build on the generally good record in this industry by turning more attention and more resources to this issue of sanitation and food-borne disease. The Food and Drug Administration is a willing partner in any effort to increase voluntary compliance with our regulations, as well as any effort to advance the public health in general.

What the Food Industry Needs from the FDA

By C. W. COOK

This Article Was Presented at the Meeting of the Grocery Manufacturers of America, Inc., at White Sulphur Springs, West Virginia, on June 21, 1966. Mr. Cook Is President of General Foods Corporation.

MY REMARKS ARE NOT INTENDED AS AN OFFICIAL RESPONSE to Dr. Goddard's address, as I speak as an individual representing only General Foods (GF). It does seem appropriate and timely, however, to share with you experiences resulting from participation in two different groups that work with the Food and Drug Administration (FDA). One is an 18-member National Advisory

Council to FDA, established during Mr. George Larrick's administration as Commissioner of FDA. I am the sole food processor on that Council. There is one drug manufacturer, men from universities and scientific organizations, one from organized labor, and so on. The other is called the Food Industry Liaison Committee. It was brought into being largely through the efforts of our good friend Clancy Adamy of the National Association of Food Chains (NAFC), with the full cooperation of Paul Willis and the concurrence of Mr. Larrick, Dr. Goddard's predecessor. That committee is composed of:

Clancy Adamy, representing NAFC;

George Koch, representing Grocery Manufacturers of America, Inc. (GMA);

Frank Depew, representing The Food and Drug Law Institute;

Milan Smith, representing the National Canners Association;

Charles Jolitz of the Kroger Company;

Henry Bison, representing the National Association of Retail Grocers of the United States;

Two member companies of GMA (Campbell Soup and General Foods). Each of these two groups has met with Dr. Goddard and certain of his associates; and Dr. Goddard has stated that he wishes both groups to continue to work with FDA.

At the one meeting of the Advisory Council to FDA since Dr. Goddard took over as Commissioner, I was asked to state my views on the following subject: "What the food industry needs from FDA to encourage and facilitate voluntary compliance with food and drug laws."

My answer is as follows.

First let me register a few disclaimers. There has been no discussion with industry leaders, so I am expressing a personal point of view, and my reactions are not the result of unhappy experiences with FDA.

It is very gratifying to know the increasing emphasis of FDA on voluntary compliance. There is widespread opinion that previous emphasis has been primarily on the policing power of this agency. I am confident that the great majority of food processing and distributing concerns are responsible, conscientious and desirous of doing the "right thing." Fundamentally, most companies today realize it is simply "good business" to conform to both the letter and spirit of FDA regulations, guidelines, etc. To do the "right thing" at all times, industry must:

(1) know and understand what is considered "right";

(2) be assured that advice and guidance are available when the issue is not entirely clear;

(3) recognize that there is policing power which can and will be used if and when necessary—but *only* if and when necessary (without any "shooting from the hip").

In considering the capabilities of industry to comply voluntarily, we must recognize that there can be considerable differences between larger firms and smaller firms. Generally, the larger firms are informed, do understand and are capable of being of help in collaborating with FDA. Smaller firms who produce and process much of the food in this nation are not always informed, do not always understand and are often lacking in technical capabilities and facilities. Information and education programs are needed to be sure that these smaller firms have guidance that is appropriate. Industry has the right to expect a reasonably literate and informed public, but must share responsibility for keeping the public informed—and up-to-date.

What Industry Expects from FDA

Industry expects FDA to be aware of and use industry capabilities and facilities, university and college capabilities and facilities and independent firms (such as Battelle Institute and others). (FDA cannot do it all by itself, should not be empire builders and should be willing to use outside facilities to handle peak loads and/or share in the total load.)

Industry expects that FDA will not be an unreasonable bottleneck. In the private sector, new developments such as product improvements which might require FDA approval, can be very important. Many times such improvements cannot be protected by patents, so the only advantage is "lead time." Undue delays in FDA approval can dissipate this valuable "lead time."

Industry expects the kind of guidance that could, and should, result from industry collaboration on: what is good "manufacturing practice"; and what is an adequate testing procedure. (Industry is wary of any collaboration because of the possible risk of anti-trust action. Seminars convened under FDA jurisdiction would be a logical approach, and I am convinced would be productive. Subjects such as salmonella aflatoxins are logical examples.)

Industry expects FDA to have a "forward-looking" point of view, recognizing that some risks must be taken if we are to make progress. In this connection, industry has a right to expect that FDA will be

readily approachable and that there will be a minimum of red tape and bureaucracy.

Industry expects progress in the area of minimizing conflict and overlapping between local, state and federal jurisdiction. This relates to standards, inspections and actions.

Industry expects FDA to conduct its operations without resorting to "headline hunting," unless that proves necessary in isolated cases. Private hearings involving industry members can be useful in many instances. Industry recognizes the need for firmness and that "crackdowns" are necessary at times. Politicians have discovered "consumers" (all 196 million of them in this country). It is popular and appealing to be their champions. Industry has the right to expect that FDA will be non-political; and I am certain that all responsible business leaders are tremendously encouraged and reassured that FDA is now headed by a man of the stature and courage of Dr. Goddard, and that the cabinet level involved is represented by the eminent Mr. John Gardner. There is reason to believe that with these two outstanding Americans in these key posts, political pressures will be minimized.

Cooperation With FDA

As a follow-up, Dr. Goddard had his top two men in the Education & Voluntary Compliance Bureau of FDA spend a day with me and GF's top scientific and technical people, exploring examples of the kinds of subjects that might lend themselves to collaborative efforts. We found the day fruitful; General Delmore said that he and Mr. Clark did also. From that discussion came the question: "How can FDA reach, most expeditiously, those companies in the food industry who might be most knowledgeable or be most affected by a new situation requiring FDA attention?"

It would seem that the Food Industry Liaison Committee, to which I referred earlier, could serve that purpose very effectively. Through its members, we should be able to identify, on short notice, those companies which could collaborate with FDA on most any problem involving the food processing and distribution industries.

Finally, I believe I do reflect the sentiment of all members of the grocery industry in assuring Dr. Goddard that we concur that the interests of all Americans can best be served and safeguarded by voluntary compliance with regulations adjudged to be right and appropriate. I am certain they would have me sincerely assure Dr. Goddard that FDA will find us responsive and responsible, especially when we are afforded opportunities to collaborate on the identification and solving of potential problems **[The End]**

What the Consumer Expects, and Receives, from the Administration of the Federal Food, Drug and Cosmetic Act

By ELAINE G. McNALLY

Mrs. McNally Is Consumer Specialist for the Los Angeles District of the U. S. Food and Drug Administration. This Article Was Given as the Annual Charles Wesley Dunn Memorial Lecture, on March 1, 1966, at the University of Southern California Law Center, Los Angeles, California.

THE CONSUMER IS SERVED BY MANY ORGANIZATIONS. The interests of these organizations are varied, and their motives are complex. Unfortunately, not all share a common responsibility for the consumer's general welfare and genuine well-being. The Food and Drug Administration has, for the past 60 years, served as the public's protector against contamination, fraud, impurities, and hazards in the basic commodities on which man's existence depends. Safety is and always must be the key word in our responsibilities to the American public. In this respect we share a common bond with the Food and Drug Law Institute and with members of responsible industry. The steady appearance of new products and the addition of new ingredients to old favorites continually raise questions relative to present day safety of foods, drugs, cosmetics and their component parts. We are motivated to seek out the answers to these questions and to resolve them effectively and efficiently by developing new and more accurate methods for determining product safety. A project of this scope and multitude requires the combined efforts and intellects of industrial technology, scientific research, and law enforcement. Working cooperatively, we will be better able to provide for each and every citizen the kind of world in which he aspires to live, and the safety he has come to expect to enable him to live and to enjoy his existence in that world.

Challenge to American Industry

The demand for satisfying, nutritious foods, potent, curative drugs, and beautifying and non-injurious cosmetics has presented a challenge to American industry, and it has answered that challenge with enthusiasm and productivity. Every hour of every day, genius is at work developing new products to intrigue the consumer and tempt him to try their contributions to the growing list of goods available in the marketplace. A weekly trip to the neighborhood supermarket can be as jammed with surprises and unexpected treats as the traditional Christmas stocking, if the consumer elects to make it so. Shopping in a well-equipped market today can be comparable, experience-wise, to Alice's well known adventure into Wonderland. New products, waiting to be discovered! Some in a "test market" stage, hoping for acceptance so that they may become tomorrow's stars of television commercials!

The average consumer experiences a feeling of expectation when trying a new product for the first time. This is especially true if he has "discovered" it and can enthusiastically and sincerely recommend it to others. The desire on the part of the consumer to be first is to the advantage of the producer. If people were not stimulated to try new products their procession into channels of commerce would indeed be slow. Manufacturers recognize the value of this "spirit of adventure" in the buying public and wisely try to protect and encourage it.

In the days of the great depression, neither the consumer nor the producer had resources for experimentation available. Consumers were satisfied with the bare necessities and manufacturers were content to have one or two accepted products moving steadily. Fortunately for all, the picture has changed drastically. Today's consumer has the price of the necessities and some left over for luxuries. He has come to accept the standard item as routine. It is readily available when he wants it. However, the pioneer spirit he inherited from his forefathers demands a challenge, so he seeks out the new, the unusual, and in some cases the exotic. This new consumer buying pattern was vividly pointed out in the March issue of "Holiday Magazine," where it is reported that the American consumer spent four billion dollars on the arts during the past year—an increase of about 130% since 1953.

Clean, wholesome, attractive, safe and nutritious attributes are not enough. These are qualities the consumer has come to expect, and

takes for granted. Today's consumer is seeking something more and he will go to great lengths to find it. When he does encounter such a product, proven or unproven, he expects perfection in his purchase, as a built-in-extra. If he doesn't get it, he becomes annoyed. The price of the product becomes incidental. The fact that the purchaser feels cheated becomes all-important. A very large turmoil can develop over a seemingly incidental purchase. Today's consumer feels that he has problems. He also feels that he is entitled to protection from and assistance with these problems.

Action by Dissatisfied Consumers

What course of action does a consumer embark on when he becomes dissatisfied with a purchase? This will depend a great deal on that particular consumer. Consumers come in as many varieties, shapes, and sizes as do the commodities offered for their selection on the supermarket shelves. How a particular consumer will elect to deal with a given incident will vary with the personal traits of that individual. From my experiences with consumer groups during the past year, I have found that the most frequent remedy resorted to is that of returning the purchase to the retailer and asking for a refund. If this is successful, the consumer often drops the matter here. In a single incidental purchase, the consumer usually experiences no difficulty. Less frequently, consumers have related the following experiences:

1. A lady returned a box of insect-infested rice to the grocer where she had purchased it that same day. The grocer told her to put it back on the shelf and take another. This irritated her even further. She did as he instructed. She has not returned to that market. She has not purchased that particular brand of rice since this incident.

2. A customer wrote a packer, whose name and address she found on the label, advising him that she had found worms in his raisins. She received no answer. A few weeks later, while shopping at her regular market, the one where she had purchased the raisins, the manager advised her that the raisin packer had sent a representative around to inquire personally about her. Was she a chronic complainer? Did she often return merchandise? Did she shop at his market regularly or was she an occasional shopper? Did he know her personally? Had the market manager received complaints from this particular customer and, if so, how had he handled them? The customer was indignant. She had not

asked for her money back; she had not even asked that the product be replaced. A few months later, at the holiday season, she received a very elegant gift pack of dried fruit from the packer. Somehow she did not feel that the true spirit of giving came with the gift.

3. Numerous consumers report that they are frequently advised by a retailer to return an opened unsatisfactory product to the manufacturer with a letter of complaint. You must return the evidence, they are told. Many report that they have experienced considerable difficulty in attempting to package for mailing an opened container of a liquid product.

4. Consumers report that they have removed foreign material from products and sent this to the manufacturer. In reply they are sent three or four containers of the product with a letter thanking them for calling this to the manufacturer's attention but implying that the manufacturer is not at all convinced that the material came out of his product.

Handling complaints in this manner is annoying and time-consuming to the consumer. Most report that it is not worth the trouble to complain and they would not bother a second time. Some feel that their integrity is being questioned. All agree that, thanks to the variety of products available today, the simple solution is to choose another brand. But, they add, this is taking the easy way out and it does not insure that the incident will not continue to occur, possibly more frequently.

What of the consumer who makes a costly purchase and, on using the product as directed by the manufacturer, finds that it does not do for her what she was led to believe it would do? The product is not returnable and she is embarrassed that she made such a poor investment. A lady recently related such an experience to me. The product was a vibrator device sold to her with the understanding that it would help her to remove excessive weight, painlessly. The lady is still overweight, after having used the device faithfully for three months and losing not a pound or an inch. The device is gathering dust in her closet and the solution to her dilemma, she has decided, is to sell the item to an interested friend at half price. A consumer-producer arrangement of this kind might be considered unethical; between friends it is accepted as practical.

Occasionally we encounter the misinformed, overly-agitated consumer who is convinced that the producer is intent on only one thing,

to make a profit. The consumer is further convinced that this profit will be derived at the expense of his health and well-being. What is more, he is convinced that the government is aiding and abetting the policies of business at the expense and eventual destruction of the consumer. This individual is prepared for battle. To effectively dispute an entire industry plus the Government, he feels the need for reinforcements, so he joins an organization. Here he finds support for his cause, others who share his thinking and are motivated to take action against a common enemy. An organization of this kind, even though in the minority, represents a real problem to consumer and producer. They spread misinformation. They contaminate others with their thinking, and they undermine confidence in the safety of the American food supply and cast suspicion on it publicly.

One of the ways in which they attempt to influence legislators is by the distribution of cards. Members are obligated to distribute these cards, in quantity, among non-member friends. They request that the cards be signed and mailed to Congressmen. One particular card is in objection to the proposed DDT tolerance levels for dairy products. On the address side of the card appears the slogan, "All Americans have the right to adequate protection from dangerous poisons." This statement is both impressive and frightening to the uninformed. This particular organization also maintains a legislative advocate in its Washington, D. C., office.

Since the beginning of time, people have been concerned about food. They still are. For some people, that concern has been simply one of supply and demand, the availability, or lack, of enough food to meet their daily nutritional requirements. In recent years in the United States, the problem has become one of overnutrition for many persons. History tells us that during periods when food was scarce, being overweight was a status symbol. The wealthy had the resources with which to buy all the food they wanted, in addition to what they actually needed. All you had to do to determine this was to look at them!

Concern About Nutrition

Medical personnel and insurance companies are continually pointing out to the American public that being overweight is a health hazard. and so a large number of consumers have become conscientious calorie-counters. People today are concerned about nutrition. In addition to being calorie-conscious, they are cholesterol-conscious, they are protein-conscious, they are vitamin-conscious, and they are

non-nutritive-sweetener-conscious. Their interest is keen. They are seeking guidance and information, but few are able to distinguish reliable information from half truths and out-and-out falsehoods.

In talking to consumers, I find that they know that a well balanced diet is essential to good health. I also find that many of them do not know what a well-balanced diet consists of. Some homemakers interpret a well-balanced diet as being one where the same dish is not served twice in one week. Many do not know that amino acids are constituents of proteins. They do not understand what constitutes a complete protein or an essential amino acid, and supplying them with a listing of the essential amino acids by name only confuses them further. More chemical terms that they do not understand! Yet they are confronted continuously by these terms in advertising claims and on labels. I am repeatedly asked if the phrases, "high in protein" or "more protein" on cereal boxes mean "complete protein."

I am amazed at the number who feel the need for daily vitamin supplements and are convinced that more vitamins, and these of superior quality, are obtained from a bottle than from ordinary foods. I am surprised at the number who feel that the kind of cooking utensil, the material from which it is constructed, better protects nutrients during cooking than does the cooking method employed. I am appalled by those on weight-reduction diets whose idea of reducing caloric intake includes no breakfast, and a piece of pie and a bottle of coke at lunch.

Confusion Caused by Chemical Names of Additives

Another area of confusion for the consumer is that of chemical additives. The use of preservatives is most often singled out for attack. "What happened to the good, wholesome, 'old-fashioned' foods, the ones that contained *no* chemicals?" he asks.

A gentleman recently brought me a packaged food he had purchased, a new product presently enjoying good acceptance by the consumer—partially due to the improved quality of the product and partially due to ease of preparation. The ingredient list on the package included such tantalizing taste sensations as sodium caseinate, propylene glycol monostearate, adipic acid, sodium citrate, hydroxylated lecithin, carboxymethylcellulose, natural flavor, salt, U. S. certified color, and BHA added as a preservative. "Now," asked the gentleman, "How much of this do I eat and how much of it eats me?"

Consumers are asking for an interpretation of the chemical terms found on labels. Salt, they insist, has a chemical name and a com-

mon name. They recognize and *trust* the common name. "Why," they asked, "can't all listed ingredients have a common name, one that we know and recognize?" It is not very comforting or informative to be told that BHA is the common name for butylated hydroxyanisole. Most accept this explanation, confident that if the ingredient were not safe as used, it would not be tolerated in food by the Food and Drug Administration.

Consumers' attitudes toward chemical names appearing on the label of an over-the-counter drug preparation are somewhat different from their feelings about food labels. Drugs, they reason, are expected to contain chemicals, but they are not yet prepared to accept foods containing chemicals. Most comment that they do not understand the ingredient listings, but they accept it as medical terminology, which, they confess, they have never understood and don't expect to. The usual comment is, "We can always ask our doctor." Some are content to accept the word of the pharmacist dispensing the preparation.

Ingredient Lists for Cosmetics

Requests for ingredient lists on cosmetic labels are being voiced more frequently by consumers. Some know they are allergic to a particular substance and feel they would have greater protection if they knew the substance was present in a given preparation. They could then select another product not utilizing the offending ingredient. Others feel that there is little, if any, difference between the $20 jar of face cream and the $2 jar of the same quantity. They would like the privilege of comparing ingredients.

The fact that consumers are questioning the information on labels is gratifying in itself. It indicates that they *are* reading labels. They are seeking information pertinent to the product so that they can best choose and profit from their selection. In today's world of sealed cans and glued packages, the only clue to the content that the consumer has must be presented on the label, and the ladies would very much like to be able to read and interpret that information properly. The law does not allow one to go shopping armed with a can opener and switchblade knife. Mrs. Homemaker must depend entirely on the message on the outside of the container to direct her in her selection of the product encased within the container. We wonder if the manufacturer is taking *full advantage* of this method of communication with the consumer. An intensive consumer education program, conducted by industry, about labels and their meaning could prove profitable to many producers.

Less Eye Appeal and More Sense Appeal

Packaging, in itself, has become big business. The manufacturer has long depended on the eye appeal of the container to sell the content. Industry sometimes employs color psychologists to determine what color combinations and what amounts of color will best attract the prospective purchaser. Artists are regularly employed to design the label, to convey a message in picture and print, to create a "desire-to-buy" atmosphere. Consumers have no quarrel with the attractiveness of the products. A few find a product so appealing that they buy it for the package alone with little regard for the real value of the content. However, there are those, and their number is growing, who advocate that some change in packaging and labeling is long overdue. They vote for less eye appeal and more sense appeal, less gift wrapping and more gift. They feel that manufacturers could better capitalize on the public's new-found pastime, label reading, by providing more accurate, pertinent and readable information on labels, and by enlarging on this in advertising. Fewer singing jingles and more helpful information aimed at a better understanding of the product and its component parts is the order of the day, they feel. Consumers tell me time and time again that they feel the remote control apparatus supplied with many television sets today is the greatest. They use it for cutting off commercials. This statement makes one wonder just how valuable these costly commercials really are.

Labels tell a story. The Food, Drug, and Cosmetic Act requires that story to be truthful in all respects. If the life-sized apricot on the outside of the can does not show a worm, the consumer has been conditioned not to anticipate finding one on the inside. The shock could be enough to prompt her to complain to the nearest district office of the Food and Drug Administration. Ladies, I have found, do not like worms in their rations, insects in their flour, or cigarette fragments in their carbonated beverages. "This," they say, "is enough to make you switch brands!"

Incidents of fatal food poisoning are rare today. However, when one does occur the impact is severe. The consumer is frightened and shocked. Consumers have been conditioned to expect they will not find this kind of thing in the American food supply. Botulism in tuna has not been forgotten. Consumers regularly ask if the canned tuna on the market today is safe. Some consumers comment that they still are not adding tuna to the family grocery list. Each holiday season we can anticipate numerous telephone calls inquiring about the safety of cranberries this year.

All told, the consumer is pretty well satisfied with his lot today. He feels there is room for improvement in certain areas, among them those we have touched on briefly this afternoon. He is sometimes overly impressed by the outer wrappings of a product and then irked by the content. Even so, he does not vote to return to the days of the "country store" when merchandise was displayed in open barrels and bins, and one could examine, even sample, the product. He likes to have his food protected from rodents, insects, and fellow human beings. He likes being able to choose from many varieties. A large number of our consumers remember vividly the days when they could choose white, whole-wheat, or rye bread, corn flakes, shredded wheat, or oatmeal. Now the varieties in these two food areas alone are stupendous!

Educating the Consumer

This is the age of the consumer. And the consumer is the first to acknowledge a pressing need for dynamic programs designed to bring him an understanding of our food supply. Educating the public so that they may protect themselves and profit from having done so is not new. Thomas Jefferson once said:

> If we think them not enlightened enough to exercise their control with wholesome discretion, the remedy is not to take it from them but to inform their discretion by education.

A rebirth and revitalization of programs aimed at adult education appears to be the order of the day. More and more adults are returning to school, and this interest in gaining knowledge is not limited to a formal education. Adults are seeking guidance and information for use in daily living. It is the duty of responsible organizations to supply that information whenever possible and wherever feasible. Consumers are receptive but not always discriminating in the information they accept and utilize. Charlatans and profiteers have long since recognized this weakness in our social structure and have a head start in shaping and developing it for personal gain. Providing the consumer with adequate and understandable answers to his questions is the obligation of science, industry, and law enforcement. To refute the unproven and the erroneous is also an essential part of this program.

Too many consumers are confused as to the real function of the Food and Drug Administration. They tend to look on it as a governmental agency that "approves" products in much the same manner as does Good Housekeeping Institute. If they are disappointed or suffer ill effects from the use of a product, they are "surprised"

that the Food and Drug Administration has permitted this product to be on the market. They are further surprised to learn that, with some notable exceptions, the FDA does not "approve" products, but takes immediate steps to assist in the removal of products of which they disapprove from the marketplace—products that are in violation of the Food, Drug, and Cosmetic Act.

Those who are familiar with the workings of the Food and Drug Administration recognize it as a scientific organization that bases its decisions on scientific fact rather than on emotion—the stock-in-trade of unethical promoters and misinformed alarmists. Scientific research presently being conducted by FDA is directed to the further understanding of the significance of trace elements, vitamins, and the calorie-producing nutrients, proteins, fats and carbohydrates, and their effect on human nutrition. New methods for the identification, determination, and control of natural and artificial food contaminants such as salmonella and other microorganisms, aflatoxins and other mycotoxins, pesticides, additives, radio nuclides and filth are being developed. We are dedicated to improving mechanisms for protecting all consumers against exposure to such health hazards.

Protecting Consumers

Much effort is devoted to protecting the consumer in a complex world. Much effort is needed to help him understand and accept the scope of that protection. The consumer's ability to evaluate and disseminate information varies with his environment, his ancestry, his education, and his experiences in living. He cannot and will not be categorized. Developing a consumer education program that will accomplish results is a difficult and time-consuming project. Some of the experiences we have had with our program in the Los Angeles District during the short time it has been operating on a full-time basis may be of interest.

We have worked with established community organizations in East Los Angeles. Here, our major obstacle has been a language barrier. There are many Spanish-speaking residents in this area, and the publications we are using in class instruction are not available in Spanish. Even though numerous leaders in these programs speak Spanish fluently, they readily admit they are not properly qualified to translate materials written in English into Spanish. If the person doing the translating is not thoroughly familiar with the subject matter, the finished product can have quite a different meaning than was originally intended. To put it simply, it loses something in the

translation. An organization concerned with community safety in the San Diego area attempted to translate this pamphlet into Spanish for the benefit of the Spanish-speaking residents of Baja, California, and neighboring communities. It employed experts to do the job. The pamphlet was reviewed, criticized, and revised on five different occasions. When the group felt it was ready for the printer, it submitted it to a young woman who speaks Spanish fluently, is of Mexican descent, and teaches English at the secondary level. On reading it, she commented, "I don't think this is what you actually want to say. It says here, 'This year we are going to poison 500,000 children.' People are going to ask why." One wonders what interpretation our Spanish neighbors get when they attempt to read the labels on cans and packages available to them in our supermarkets. This may present a clue to why they are reluctant to supplement their diets with many of the new foodstuffs available to them. Those who have a poor understanding of English tend to favor the homemade Mexican dishes composed of foods they are used to and understand and trust.

Our senior citizen population is rapidly increasing. As people age, their eating habits tend to change, and it is often difficult to stimulate an interest in new food products. The oldsters are more impressed with patent medicines, vitamin supplements, and so-called "health foods." Many of them have hearing and vision deficiencies, difficulty in getting around, and transportation problems. A shopping tour, to them, is a chore rather than an enlightening experience. Again, they are inclined to stick to the old and familiar. When they are tempted by a friend to try a new product, it is usually recommended as "a cure for what ails them" instead of as a taste treat that would put new interest in their diet and provide a source of nutrition. The attitude of many in this age group is: We have lived this long without it, so who needs it? These people are prime targets for medical charlatans, and door-to-door "health peddlers". The brand name is about the only information on a label that many of these people can read without difficulty.

Perhaps the person most receptive to new products and reliable information is the young homemaker. Usually, she is on a budget. She is intent on getting full value from her purchases. She generally has pre-school children. She is interested in protecting their health. She has not been away from school very long and is still receptive to the learning process. She is interested in community affairs. Often, her husband is just getting started in a local business or professional position. I recently had occasion to talk to such a group

in Santa Maria. All of these women ranged in age from the early twenties to the early thirties. All were college graduates and all had pre-school children registered in nursery school. They were most annoyed by what they termed "deceptive advertising gimmicks". They wanted to know what protection they had under what law, and what new laws were needed to give them the protection they feel entitled to, but, in their opinion, are not receiving.

We have directed some of our educational activities toward junior and senior high school students. Usually, this is in conjunction with classes in health education. At this level, the student is undergoing the normal learning process and is receptive to new information. I have been asked to speak to adult groups because some member's child heard me speak at school.

In addition to feeling the need for information, consumers need to know where to turn for specific information. We receive many inquiries at FDA that are not, in reality, FDA's concern. In some cases, we have persons on our staff who are qualified to answer the questions. In any event, we attempt to help consumers find the answer by referring them to a reliable source.

We have offered a somewhat sketchy outline of our attempts to provide the consumer with the kind of information he apparently feels a need to have. Our program was originally designed to promote and maintain an exchange of information between the Food and Drug Administration and the consumer. This is being accomplished. We encourage responsible industry to join in an effort to provide the consumer with *reliable* information about the products offered to him in today's marketplace. Who is better qualified to provide reliable and helpful information about a product than the producer of that product? His technological know-how, his scientific research, planned and developed the product to a marketable stage. Why shouldn't this same invaluable information, presented in an understandable form, serve to promote and maintain consumer acceptance of that product? Consumer education is not an over-crowded field. In the past, it has been an overlooked, even ignored field. We welcome and encourage all and any reliable participation in this most needed and important area of endeavor.

The idea that you can give the consumer anything and he'll never know the difference is outmoded. Consumers are willing and anxious to listen and learn, but not in silence. They are no longer willing to accept without questioning. They are speaking out, and the producer who elects to listen may well profit from having done so.

[The End]

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