VOL. 21, NO. 1 / JANUARY 1966

Food Drug Cosmetic Law JOURNAL

Papers Presented at the
1965 Joint National Conference of
The Food and Drug Administration and
The Food Law Institute, Inc.

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; 3 years, $49; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

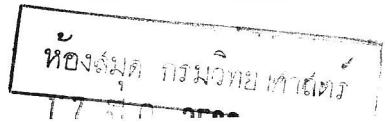
January, 1966
Volume 21 ● Number 1

Second-class postage paid at Chicago, Illinois, and at additional mailing offices.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . January, 1966

VOLUME 21 NUMBER 1



FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

1965 FDA-FLI Conference.—Some of the papers presented at the Ninth Annual Joint Conference of the Food and Drug Administration and The Food Law Institute are featured in this issue of the JOURNAL. Additional papers will appear in later issues. The Conference was held on December 6, 1965, in Washington, D. C. The theme was Plans and Progress for Industry Information, Voluntary Compliance, and Consumer Education.

In the "Opening Remarks," beginning on page 4, *Alexander N. McFarlane* discusses the role of the FLI as a catalyst in joining together industry, government and the consumer. The purpose of the meeting was to "provide a forum for the discussion of laws which bear directly on the operation of some of the nation's largest enterprises and all of this country's 195 million consumers," and to bring about understanding and cooperation between industry and government.

Theodore R. Gamble discusses the "Food Industry and Consumer Protection" in his article beginning on page 6. He states that as the largest industry in the world, the food industry, is committed to voluntary compliance and self-regulation in the consumer interest.

"Highlights of the Report on State and Local Food and Drug Programs," beginning on page 13, concerns the use of resources by public agencies in the food and drug field, the need for intergovernmental coordination, and the responsibility of public protection. The author, *E. F. Ricketts,* is the Associate Director of the Public Administration Service.

The background for and the effects of the Kefauver-Harris Amendments of 1962 are discussed by *John T. Kelly.* In his article, "Three Years Later," beginning on page 21, he explains the problems resulting from these amendments.

The article beginning on page 28, "Progress in Research—A Question," also concerns the Drug Acts of 1962. *Robert W. Ballard, M.D.,* discusses the six major categories covered by regulations.

The role, objectives, and responsibility of the pharmaceutical industry are analysed by *Anthony T. Buatti* in "An Appraisal of Progress in Drug Marketing," beginning on page 33.

William C. Warren, Dean of Columbia University Law School, discusses the past, present, and future of congressional investigations. His article, "Congressional Investigations: Some Observations," begins on page 40.

"Food and Drug Administration Industry Information Programs" deals with the importance of better communications between the FDA and regulated industry. This article by *Harold O'Keefe* begins on page 52.

According to *A. D. Davis,* "planning is the keystone of problem development." In his article "Food and Drug Administration Plans and Programs," beginning on page 57, he discusses a five-year master plan for the FDA.

Vol. 21, No. 1 January, 1966

Food·Drug·Cosmetic Law
Journal

Opening Remarks

By ALEXANDER N. McFARLANE

The Following Remarks Were Presented at the Food Law Institute—Food and Drug Administration's Ninth Annual Educational Conference at Washington, D. C., on December 6, 1965. Mr. McFarlane Is the Chairman of the Food Law Institute.

THE PURPOSE OF THIS MEETING—as it has been the purpose of each of the previous eight meetings—is to provide a forum for the discussion of laws which bear directly on the operation of some of the nation's largest enterprises and all of this country's 195 million consumers. The ultimate purpose of discussion is, of course, to encourage understanding and cooperation between government and industry in the consumer interest.

The Food Law Institute (FLI) was founded in 1949, specifically to promote the development of essential knowledge of food, drug and related laws. At its organization meeting this purpose was endorsed by the U. S. Commissioner of Food and Drugs and by the President of the Association of Food and Drug Officials of the United States. There are today about 50 companies which are industry members of FLI and several public members, representing the leading official food law organizations in the United States, France and Great Britain. In addition, there are two groups of trustees, one drawn from industry and the other from men in public life, including government.

Many of you are well aware of all this, but it serves to underscore the FLI's historic role as a catalyst in joining together industry, government, and the consumer in considering common problems. And this role was never more important than it is right now.

I hope I am not the reincarnation of the original Pollyanna when I express the belief that things will work out for the best—that as our economy moves further in the direction of concern for the consumer interest, both government and industry will serve their proper roles. Because I believe in the ultimate sound judgment and good intentions of people.

But I am not unmindful of the stresses and strains between government and business. These are not easily shrugged off. But neither is there any reason to be overwhelmed by them. If it is possible to take a detached view—and sometimes this may seem almost too much to expect—these differences can be seen as one result of change, the by-product of which always is stress and strain.

The particular change to which I am referring is a new emphasis on the rights of our citizens. Now, the concept of responsibility to the public is nothing new either to government or industry. We have been asserting all along that both government and business are of the people, by the people, and for the people. The old emphasis was however on *for* the people and we both acted on their behalf. Then something began to happen. Maybe it was that the decibel level of public opinion was raised, or maybe it was that our listening devices improved, but for whatever reason the voice of the citizen is being more directly and distinctly expressed in both government and business today. We have both encouraged these expressions because we know it is through them that we can best carry out our responsibilities to the public. But at the same time this situation is building up pressures exerted by the public on both of us, and then by each of us on the other.

The danger, as I see it, is that in a more highly pressurized atmosphere we may end up vying with each other for public support. This would be a tragic error, because we are not, nor should we be, in any way competitive. We are performing not the same function, but complementary roles, and in both cases we are functioning only by reason of the fact that we serve the public. There is no reason either for building fences, or for positioning ourselves on their opposite sides. There is even less reason for either of us to attempt to diminish the public confidence in and support of the other, for the entire superstructure of our economy rests on the foundation of public confidence in both government and business. **[The End]**

The Food Industry and Consumer Protection

By THEODORE R. GAMBLE

Mr. Gamble Is the President of the Pet Milk Company, St. Louis, Missouri, and Chairman of the Board, Grocery Manufacturers of America.

THE FOOD INDUSTRY TODAY is the nation's, and the world's, biggest business. It is estimated that next year the industry will do close to $90 billion in total sales. This figure alone makes it obvious that neither I nor anyone else can speak collectively or authoritatively for the entire food industry. But, by virtue of the office I hold as chairman of the board of the Grocery Manufacturers of America (GMA) and as a keenly interested observer of, and participant in, industry and government activities through the years, I do feel some of the points I want to make will be more than just personal comments.

The first and most important thing I want to make clear is that the food industry endorses vigorous enforcement of existing laws. In addition, the industry—both in its public statements and in its day-to-day actions—has committed itself to a continuing policy of voluntary compliance and self-regulation in the interest of the consuming public.

The benefits which have been derived by consumers as the result of government regulation of foods and food processing have long been self-evident. The standard-making authority as well as certain police powers which have been delegated to regulatory bodies by legislation serve well the objective of assuring the wholesomeness and nutritive integrity of our country's food supply.

At the same time, however, the food industry itself has done a truly outstanding job in regulating the quality of the food it manufactures and sells. In fact, I feel it is safe to say that government regulation alone would have been unequal to the task because of inherent limitations of staff, funds, physical facilities and equipment. The government could not have done the job required of it without the cooperation and the assistance of the food industry itself.

And there is yet another even more important side to this triangle—the consumer herself. After all is said and done, she is the real arbiter of food quality. There are those who try to portray the average shopper as unknowing, easily-hoodwinked, unsophisticated and gullible. Just try selling Mrs. Consumer anything, and you'll find out differently! With amazingly few exceptions, today's buyers are intelligent, aware, discriminating, discerning and well-qualified to make their selections wisely. Some buy for price, others buy for quality, others for a combination of these factors. But, the point is, they *know* what they are buying and *why*.

The consumer is the only one who dictates to the food industry—not the other way around. Every time she picks one product off a shelf and rejects a competing product, she is helping to determine the success or failure of both the products and of the companies making those products. The quality and integrity of foods are essential to the growth and progress of every food processor, distributor and retailer.

Revolution in the Food Industry

There has been a revolution in the food industry since World War II, and perhaps one of the reasons some persons are critical of our industry is that they don't really understand this revolution. There has been a rapid trend away from the use in the home of basic agricultural commodities in meal preparation. The pattern of food consumption has moved overwhelmingly toward *prepared* foods. These offer special convenience features, time-saving in preparation and an almost incredible increase in variety and availability made possible by widening patterns and new methods of distribution, storage and packaging.

This revolution has had the effect of removing food preparation substantially from the home to the factory. It has created entirely new problems of regulating quality, safety and wholesomeness of food. It has increased almost beyond belief the number of food items available to the consumer today. Around 8,000 different food items are sold in today's average supermarket.

The revolution has brought into use a whole new technology of food processing, new equipment, and the common use of literally hundreds of food additives. It has created a new industry consisting of suppliers of ingredients to perform the functions of supplying essential nutrients, preserving foods by controlling microbiologic quality, inhibiting flavor degradation, extending shelf life, and stabiliz-

ing physical structures—to enumerate just some of the important aspects of the newer food science that has grown up in recent years.

This revolution has created a situation where the task of regulating quality and safety in food preparation has outstripped the resources, money, manpower and technical facilities of our government agencies—local, state and federal. This does not mean these agencies are no longer important. On the contrary, they are still extremely important. They must set standards for foods, establish basic criteria for safety, set guidelines for nutritional properties, enforce rules prohibiting adulteration, develop criteria for plant sanitation, and, to the limit of their resources, police the food industry and, where necessary, institute enforcement procedures against any transgressors.

Self-Regulation

In fact, the food industry has consistently supported and will continue to support the requests for adequate funds and personnel for these agencies. However, without the day-to-day self-regulation of its products by the responsible food industry, I think it is only realistic to say that the efforts of our fine food and health agencies would fall far short of their desired goals.

None of us today is naive enough to state that this self-regulation is purely altruistic on the part of the food industry. Obviously, the food industry's increasing emphasis on quality control and quality improvement programs is motivated in great measure by enlightened self interest. Food processors are recognizing that they can deserve and retain public esteem only if they respect and fulfill their responsibility to the public welfare.

Although it is hard to obtain exact figures a conservative estimate is that leading food processors spend more than $100 million annually on quality control alone. This figure does *not* include the much larger sums spent on development of new products and on applied research.

Quality control was the forerunner—by several decades—of research and development in the food industry. As prepared foods grew in variety and usage, concurrently with the development of pure food laws, the primary requirement by the food manufacturers was for methods to insure consistent quality and safety of their products. This introduced into the food industry a new type of scientifically and technically trained personnel. These men and women started with basic housekeeping and sanitation in processing plants. They gradually expanded to embrace monitoring and compliance with food and health regulations, standardizing of finished products and production

practices, devising methods for cleaning and care of equipment, and developing specifications for all ingredients with respect to grade, purity, physical, chemical and other properties.

It is interesting to note, in passing, that today's quality control techniques use statistical methods of "in-line" sampling and testing so that, hour by hour, on the production line, it can be determined whether a satisfactory product is being made. This preventive measure contrasts with the old system of testing finished batches of product in the warehouse. Today's methods enable food processors to catch a problem far sooner.

Working with the Food Protection Committee of the National Research Council-Academy of Sciences, a food industry liaison panel has financed and brought forth the new *Food Chemicals Codex* which fixes standards and specifications for chemicals used and necessary in the processing and preservation of foods.

Programs of self-regulation have taken shape and are continuing to take shape in virtually every segment of the food industry. There are so many that time prevents my listing them all, but I do want to cite a few specific examples to you to help prove my point.

To help assure member compliance with the law, the National Canners Association has a continuing program and publishes a comprehensive manual for its members on food and drug legislation. The manual is done in a loose leaf manner, and it is constantly being updated.

The American Bakers Association has a somewhat similar manual and program.

The Millers' National Federation has an extensive program as well as a handbook on compliance with the Food and Drug law. Much of this is devoted to labeling practices and regulations.

The Corn Industries Foundation has a program and a detailed publication relating to the products of that major industry.

The National Association of Margarine Manufacturers has an on-going program among its many members, including both an up-to-date compilation of all laws and regulations as well as a consumer information program.

The International Association of Ice Cream Manufacturers publishes a loose leaf service for its many members called the Law Reference Service. The format is that of a code based on federal and state laws. Guidelines for labeling and packaging form a large part of this service.

The National Association of Frozen Food Packers, working closely with the Association of Food and Drug Officials of the United States, has done an encyclopedic job on the entire Food and Drug Act. The organization is developing standards for frozen foods. It holds seminars in various cities for instruction of personnel in quality control, microbiological standards and on possible hazards to consumers. Instruction is provided by outstanding industry experts. The association has done an exceptionally thorough job in developing industry standards for labeling and packaging.

There has been a great deal of progress by the National Conference of Weights and Measures. The food industry has worked very closely with this group in arriving at a consensus on placement, visual prominence, and a schedule of minimum type-sizes keyed to the square-inch area of the principal display panel on various food packages. Many prominent figures in the food industry have been active in this work at the national level, and perhaps as many or more have been equally busy in this work throughout the various states.

GMA has been very busy in two basic areas. This large, broadly-based industry group has been working within its membership to develop ever-higher standards of performance in all aspects of food processing and marketing. GMA has also been active nationally for many years in the field of consumer information and education, providing guidelines and a great many other pointers to enable consumers to buy food products more intelligently and economically.

GMA has also been active in encouraging its members in self-regulation of packaging and labeling and is currently updating its programs covering this important function. GMA has done much to assure acceptance and extension of the so-called Model State Weights and Measures Regulation of the National Conference of Weights and Measures.

These are but a few examples of industry's efforts to do a thorough and conscientious job of protecting the consumer. I could cite many more.

Because there is adequate local, state and federal legislation; because there is self-regulation in the food industry; and, because the consumer herself exerts a powerful form of control, we in the food industry submit there exists today no demonstrated need for additional legislation. In fact, some recently-proposed legislation would seriously upset the delicate balance of regulation and self-regulation which has done so much to benefit consumers everywhere.

The "Consumer Movement"

We are well aware of the so-called "consumer movement" in this country. Our industry deals with tens of millions of consumers daily, so we believe we too know a few things about consumers. Our experience convinces us that there is more shadow than substance to this supposed consumer revolt.

A few people are trying to tell the nation that the consumer needs protection from business. They would substitute complete government regulation for business integrity in the marketplace. If they succeed, they will destroy competition. If they succeed, this will assure consumers grocery store shelves where all products are the same size and shape, with the same standardized contents and the same labels. If they succeed, they will virtually deny consumers any right of choice.

Competition is vital to the consumer! It brings new, improved, and more diverse products in a constant parade across the grocery shelves of this nation. Legislation which would substitute bureaucratic judgment for the judgment of the consumer at the point of purchase would stifle innovation and creativeness in new-product development and packaging. Competition has helped make our supermarkets the envy of the entire world with their almost endless variety of attractively-packaged products. Certain newly-proposed laws would be a dangerous step toward standardized products and packaging which would reduce shopping to a dull, dreary routine.

Fortunately, there has been no real public clamor for such legislation. The series of regional consumer conferences held last year are a case in point for they gave no indication of any serious consumer dissatisfaction.

There were some consumer complaints evident, but these were interesting to hear. Almost without exception they related to purely local problems. They were concentrated in such activities as home and automobile repairs, used car sales, dishonest itinerant salesmen who "work" one city and then go on to another and similar but strictly isolated business practices.

The Better Business Bureaus, both nationally and locally, can verify this pattern of consumer complaints. It always mystifies me why those who constantly seek new and restrictive legislation fail even to consult such complaint-oriented organizations as the Better Business Bureaus to find out where the real trouble spots are. From experience, we know that amazingly few of the problems are food-related ones.

Still another reason for hoping that there will be no legislation forthcoming which would hamper and inhibit our competitive business society is the growing rapport which has been developed in recent years between business and government. This has not been a one-way street. Rather, government has come to recognize more clearly the aims and methods of business and realizes business is essentially honest and legitimate in the conduct of its affairs. By the same token, the era of the businessman who is irritated by all government activity is becoming a thing of the past. Today's businessman expects and welcomes the participation of government in our lives.

I have the very real privilege of serving as a member of the Business Council. As a member of this group I have the continuing honor to meet regularly with government officials from President Johnson on down. As a result of my participation in this group, as well as elsewhere, I can say without hesitation that the climate between business and government today is better than it has been for perhaps forty years. This is one of the basic reasons why this country is prosperous today. We would ignore this relationship at our peril.

This is why it is our hope in the food industry that new appointees to important governmental positions are ones sympathetic to this newly-developed relationship rather than ones hostile or antagonistic to business. While policy is set from the President's office on down, the way policy is carried out and the environment in which it is implemented can often adversely affect many vital decisions.

We in the food industry are proud of our record of performance, while at the same time we always are trying to do an even better job. Americans enjoy a higher standard of living—and eating—than ever before in the history of the world. Our people can buy their food for a smaller share of their income than ever before—only about 18½ cents out of every after-tax dollar. Just 15 years ago, this figure was 26 cents. In Russia today, the comparable figure is 53 cents.

The average American housewife today spends only 11 hours a week cooking for her family—less than half the time it took her before World War II. What's more, she feeds this family with far more nutritious, far more attractive and far better-tasting meals than grandmother ever thought of creating.

The American consuming public takes this kind of progress for granted today and expects it to continue. It *will* continue—but only if we likewise continue to have a successful working partnership between government and business—with the consumer continuing to enjoy the right of free choice in the marketplace. **[The End]**

Highlights of the Report on State and Local Food and Drug Programs

By E. F. RICKETTS

Mr. Ricketts Is the Associate Director of the Public Administration Service.

AS I HAVE TAKEN A BACKWARDS LOOK at the study's findings and recommendations, it has seemed to me that three themes may be considered as central ones for the purposes of a quick summary. These are:

First, that public agencies in food and drug work have considerable opportunities for making better use of the resources already available to them. Their obligation to exploit these opportunities is at least as great as their duty to seek additional resources when they become convinced that more ample means are needed.

Second, that a broadly coordinated and balanced partnership among the several levels of government—national, state, and local—and among the various public agencies at each governmental level is an indispensable requirement if good use is to be made of whatever resources may be at hand.

And, third, that governmental agencies do not have exclusive responsibility to the public in this field. This responsibility is and must continue to be a shared responsibility, with government, the regulated industries, and the public each contributing more substantially to the satisfaction of public needs.

Use of Resources

Let me talk first about the matter of the use of resources. In stressing that there are opportunities for better use of the means avail-

able to food and drug programs, I do not wish to encourage the inference that the study found all state and local food and drug agencies adequately endowed with money, human talents, and the things that money can buy. The contrary was evident in many agencies and in many ways, ranging through number and quality of people, suitability of laboratory facilities, and sufficiency in the budget categories of contractual services, materials, supplies, and equipment.

As we think about the use of resources in attaining public goals in relation to food and drug supplies, it is important that we have in mind a full and realistic concept of what program resources consist. Such a concept must include not merely the money, people, and physical facilities of official agencies. It must in addition comprehend at least the goal-directed motives and activities of the regulated industries and of the interested professions, for these represent an important body of capital available for the prosecution of food and drug programs.

With resources so conceived, their use must be considered from at least three points of view. First, we must think of how the aggregate of publicly allocated resources—those that come from appropriations and dedicated revenues—are used among all the governmental levels and by the federal government as a whole, by each state as a governmental unit, and by each city and each county. Second, we should consider the employment of public funds by individual agencies. Finally, we should think of how well and fully food and drug agencies are utilizing their outside capital.

The aggregate use of official resources is especially—but not solely—a subject for attention in relation to food programs. For the food industry is not a collection of unrelated isolates—a dairy farm, a feed mill, a poultry processing plant that ships across state lines, a catering firm, a fancy grocery in an exclusive suburb, or a grubby restaurant in a central city slum. The industry is, increasingly, one of unity, and those few items that reach the consumer in nature's original packages have themselves been fashioned for content, form, and color.

This unity is confronted at all levels of government and in many individual state and local governments by a fragmentation of responsibility that may once have corresponded with the realities of the regulated industry but certainly no longer does. This fragmentation is maintained by the requirements of particular laws, by patterns of dedicated revenues, by the natural drives of separate bureaucracies for growth and survival, by the tenacity of occupational groups in seeking

to retain and if possible expand their vocational domains, and by the comfortable relationships that have developed through the years between branches of industry and the agencies that serve or regulate them.

This situation stands as an almost insuperable barrier to a comprehensive assessment of the total task that a multitude of public agencies together share. Because of it, questions that should be are never seriously asked. Does it make sense, for example, to spend as much on feeds as on foods, or to spend so much on continuous inspection of fewer than a thousand meat packing plants and so little on following the products of these plants and those of thousands of other smaller establishments to the point of retail sale? In effect, the most productive employment of the full range of resources now available is almost a matter of chance.

The fragmentation that characterizes the broader, intergovernmental scene—embracing federal, state, and local agencies—repeats itself in varying degrees among the states, although it should in fairness be reported that a good many of the states have made substantial progress toward matching the unity of industry with organizational unity for the conduct of regulatory programs. In individual departments of state and local government, poor use of available means is evident in a number of ways. These variously include the lack of information on subject establishments, how many there are, what they do, and where they are located; the inaccessibility or incomplete use of information reflecting the agency's own experience of what problem areas deserve the most attention; supervision that doesn't supervise; and others. Many of these shortcomings can be charged up to insufficient resources, but by no means all of them.

It is especially appropriate that a conference which brings together representatives of industry and government should be encouraged to think about the opportunities of a fuller use of what I have referred to as the outside capital of regulatory agencies. Such use is unfortunately meager. The possibilities that should be explored include, to name a few, ways in which the quality and performance control programs of individual companies might be meshed with those of public agencies so that they are complementary and mutually supportive, the possibilities of at least informal accreditation of such programs, and the utilization of industry training programs and skills for enlarging the capabilities of governmental employees.

Need for Intergovernmental Coordination

A second pervasive thesis of the report is that a coordinated and balanced partnership among and within nation, states, and local units should be achieved. This position is one towards which I had an affirmative, personal bias long antedating the initiation of the study. It is, however, a thesis which has a more solid foundation than one man's bias. First, it is based upon the reality that ours is still, more or less, a federal form of government. In the field of governmental food and drug work, more than in most areas of governmental action, our federal system is characterized by an overlapping, within each state, of state and federal legal authority and program activity. Some lawyers no doubt are convinced that yesterday's dissenting opinion will be tomorrow's binding constitutional doctrine, and that federal preemption of the field is not far off. It seems more likely, however, that both the Congress and the Supreme Court will continue to be very reluctant to abandon the positions that underlie the present duality of jurisdiction that prevails in the regulation of foods and drugs.

Such reluctance is probably soundly based, and possibly stems from the beliefs that the size and diversity of our nation are such that a true and meaningful federalism is the best approach in attacking the problems of our society and that it is, among other things, a form of insurance against inevitable though unpredictable breakdowns at one or the other level. But this insurance will pay off only if there is strength and capability on both sides, and a significant enlargement of the authority of one governmental level is likely to produce a corresponding debility on the part of the other. The recent northeastern blackout illustrates the point. The governmental weakness, if any, in this instance was the federal government's; the impact, however, was local, and it was local employees who promptly and effectively responded to the emergency, not those of the federal establishment.

Assuming that this duality of legal responsibility continues to be a feature of our constitutional system, the need for a coordinated and balanced partnership among the several levels of government is a kind of corollary of the first principal thesis, that in the aggregate our public agencies in the food and drug field are not doing as well as they might do with what they already have.

With this as a second principal theme, it is not surprising that our report offers several recommendations pointed toward fostering coordinated and balanced intergovernmental action. These include recommendations that the respective areas and types of responsibili-

ties of the several levels of government be adjusted to differences among them in regulatory capabilities. Thus, we recognize that no state or local agency alone can marshal the richness of scientific talent and social wisdom that are needed for prudent decisions about the safety and efficacy of drugs or the limitations that should surround their distribution. Only a federal agency can assemble from within itself and from the entirety of the scientific and industrial communities talents sufficient to the task of deciding, for example, what degree of benefit for some people justifies what measure of risk for others. In respect to foods and feeds, by contrast, we take cognizance of the substantial resources and achievements of agencies in many of the states and urge that steps be taken to further strengthen present capabilities and to enlarge our present reliance upon the states and their local units. Our recommendations also take account of obvious differences among the states in their potential for contributing meaningfully to these governmental programs. And, in addition, we express some skepticism about the practical applicability of the doctrine of home rule in giving broad freedom in policy determination and independence in administration to smaller local units, in view of the complexity of the scientific foundations, the technological practices, and the economic organization that characterizes the regulated industries.

Somewhat regrettably, we discovered no practical way of penalizing the public and official indifference of some of the wealthier states toward fulfilling their obligations for making significant contributions to these programs. Indeed, at times we were tempted to believe that the size and importance of a state's food producing and processing industry has less to do with the quality of its food protection program than the public identification of a state with its food products, as Wisconsin is with dairying.

Public Protection is a Shared Responsibility

The emphasis which our study necessarily placed upon official policies, programs, and administration perhaps accounts for the circumstance that, in retrospect, I find least explicit in the report a third major theme—that responsibility for health and economic protection of the public in relation to its food and drug supplies is not by any means exclusive with official agencies.

From time to time during the conduct of the study, we were impressed that some food and drug officials are convinced that they alone

stand guard against hazards to the consumer's health and pocketbook in his purchase and use of food and drugs. It is not surprising that the continuing duty of looking for the imperfections of these industries should make some officials conclude that their responsibility is both sole and unique in this respect.

This is not the case, however, nor should it be permitted to become so. It is necessary only to remind oneself that governmental regulation of foods and drugs is based upon selective attention, selectively applied, and that this has by and large been a successful system. One should also recall the constructive operating policies of many regulated establishments, the evident professional integrity of industry research staffs, and the sporadically constructive interest of individuals and groups in the professions of law, medicine, and the food sciences.

The sense of a shared responsibility is also apparent among members of the consuming public, in their individual efforts to inform themselves, to shop prudently, and to make their dissatisfactions known to purveyors by withholding patronage and presenting complaints to sources of supply. One might even profitably speculate about whether such events as last summer's disturbance in Los Angeles are in some small measure expressions of consumer dissatisfaction.

Despite these evidences of a conscious sharing of responsibility to the public, there is reason to believe that industry, the professions, and the public, along with government, are not doing as much or as well as they might.

Our statute books, for example, are cluttered with antiquated, anachronistic, and conflicting provisions on foods and drugs; local ordinances go off in one direction, state laws in another; rules and regulations that amplify the decisions of lawmakers often are poorly drafted, badly organized, unavailable to those they affect; and so on. The easy assignment of responsibility for this state of affairs is to legislative bodies. This easy course is pretty unrealistic; while legislatures respond to widespread public demands, we all know that much of the legislative response is to the more limited group that has an interest and actively pursues it.

In this legal area, surely both regulated industries and the legal profession are remiss. It is industry's representatives that most vociferously proclaim the need for uniform, consistent, and clear expressions of public policy. It is the legal profession that claims a peculiarly public status, has the greatest mastery of this field, and is

numerically the largest single occupational group represented among our state lawmaking bodies. The cynic's judgment is tempting, that the legal profession is made up of people who are officers of the court only for state occasions but are wholly and narrowly client-oriented in their day-by-day behavior, or even that lawyers are the ones who benefit most from the arcane nature of the law.

It is difficult to be precise about the nature and extent of the public's responsibility for its own protection, and there are so many different publics, whose needs and capacities for self-protection range so widely. These vast differences are represented by the contrasting circumstances of the residents of Chicago's northern lakeshore suburbs and of those who inhabit its teeming south side. There are also the difficulties of reconciling the regulation of economic practices that are disadvantageous for the public with some of the prevailing values of that public. One must nevertheless accept that the public or substantial segments of it have the duty of helping protect themselves, for the logical alternative is a system of governmental surveillance that is comprehensive and complete and extends from the properties of the soil to the end of the uplifted fork.

Surely one of the most difficult tasks confronting both the regulators and the regulated is that of deciding which public needs what degree of economic protection, how that protection may be best accomplished, and by whom. It is more than disappointing that so little thought has apparently been given to this problem, in view of the possibility that its neglect may lead to a pattern of comprehensive regulation that is pitched to the level of those who are least capable and most in need of assistance.

Conclusion

In conclusion, a general observation seems pertinent. It is not particularly novel, but it concerns matters about which we should from time to time remind ourselves.

The enlargement of government's sphere of responsibility and action is not a socially useful end in itself, and it should take place only in response to an unsatisfied public need. When an enlargement of the governmental sphere does occur, it is likely to take the form of a hasty reaction to what is sensed as an emergency situation. Thus, social and economic deprivation has been with us for a long, long time. We had, for nearly a generation, assumed that somehow public programs addressed only to acute financial need, a mere symptom

of deprivation, would take care of the situation, even though these programs but rarely and only slightly touched the causes of deprivation. We then found ourselves suddenly, and at times violently, reminded that palliatives are not remedies. So, new programs were pieced together, new agencies created, and new patterns of relationships among governments introduced, all with consequences that no one can now fully perceive. There is one consequence we can be sure of, however—that there will be further complications in a governmental structure that is already so complex that increasingly we can neither comprehend nor greatly influence it.

I do not imply a parallel between the food and drug and some of our newer governmental programs. Yet a part of the risk is there; this is that if the regulated industries, the interested professions, and the numerous governmental agencies are not more thoughtful and thoroughly cooperative in meeting the responsibilities they share, we must anticipate considerable expansion of governmental action in our present environment of an expanding political appeal for consumer protection. **[The End]**

SECRETARY GARDNER RECEIVES REPORT ON FDA

The committee set up by Secretary Gardner in November, 1965, to reappraise The Food and Drug Administration, has submitted its report. The committee concluded that the main problems of the FDA come as a result of its enormous growth and the number and complexity of the problems with which it must deal. It found there is a need for a clear set of policies, a need for a strengthening and re-orientation of management, and a need for strengthening the scientific resources and capabilities of the FDA.

Furthermore the members of the five-man committee agree that the Commissioner, Deputy Commissioner, and Associate Commissioner for Science should be seen as a team trying to attain strength in management and scientific competence. It is essential that at least one of these officials have a scientific background. (This recommendation has been implemented by the appointment of Dr. James L. Goddard as new FDA Commissioner.)

It is also essential that there be a stronger tie between the scientific activities of the FDA and the outside scientific community. In addition, there should be a strengthening of the internal scientific resources.

Among the recommendations in this area are that additional scientific talent be brought into the agency, that FDA scientists have more opportunities for research, and upgrading of skills, and that greater use be made of the scientific resources of the Public Health Service. It is also recommended that a scientific advisory committee be established to advise the Commissioner on difficult policy issues.

Three Years Later

By JOHN T. KELLY

Mr. Kelly Is the Legislative Counsel of the
Pharmaceutical Manufacturers Association.

THAT THE KEFAUVER-HARRIS AMENDMENTS OF 1962 changed very substantially the drug provisions of the Federal Food, Drug and Cosmetic Act cannot be seriously disputed. Nor can it be disputed that they have also affected everyone and everything having anything to do with drugs—their discovery, research, clinical investigation, manufacture, distribution, promotion, use, etc. Moreover, to administer them, the government has had to expand its forces very considerably. Indeed, these amendments have meant something for almost everyone. For example, for lawyers they have provided full employment. And for certain writers, they have provided the opportunity of becoming part of industry—the book publishing industry.

Three years is not a long time. But perhaps it has been long enough to enable some to forget who stood for what when these amendments were moving through the halls of Congress. Lest we forget then, while we judge the present, let us also remind ourselves where industry stood in 1962 and what it supported. Recent statements on this score, by persons who should know better, have been somewhat confused. And, in their confusion they may be misleading others. It would be tragic indeed if these statements would have an adverse effect on the kind of relations that should exist between industry and government. The record is there for anyone who may wish to examine it. So let's take a look at it.

Background of The Drug Amendments of 1962

To begin with, The Drug Amendments of 1962 did not derive from a single bill in the 87th Congress, but from several. There were two distinct versions of S. 1552, the bill number which was carried

through to enactment. There were two separate reports on S. 1552. There was H.R. 11581, and a House report on it. There were other House bills, including H.R. 6245, which was referred to and considered by the House Judiciary Committee. There were hearings before three committees of the Congress. Out of this mix came the bill which became the law. Of its provisions, industry supported the following:

1. Pre-market Showing of New Drug Efficacy.

(The Pharmaceutical Manufacturers Association (PMA) supported the requirement that a new drug should not only be safe but that it be shown to be effective for the uses which the manufacturer claims for it.)

2. Current Good Manufacturing Practices.

(The Food and Drug Administration (FDA) supported PMA's position that the standards must not be extreme or so unrealistic or unreasonable that they can be met by no one.)

3. Authority and Power to Standardize Names.

4. Broadening FDA Inspection Procedures.

5. Making FDA Inspection Periodic and Mandatory.

(PMA proposed this one requiring FDA to make a regular inspection of each manufacturing establishment at least once every two years.)

6. Annual Registration of Manufacturers.

(PMA also proposed this one requiring every drug processor, manufacturer, or packager to register annually if his drugs are used in intra or interstate commerce.)

In relation to other provisions such as procedural changes concerning new drugs, added grounds for withdrawal or suspension of approval of new drug applications, submission of records and reports of experience on new drugs, and control of advertising, the industry sought amendment or modification of proposed language. In quite a few instances we were not (to put it mildly) wholly successful. Some changes, however, were worked out.

But even though industry did not agree with the language of many provisions, its disagreements did not cause it to oppose the bill's enactment. As a matter of fact, industry had a "moment of truth" on this very issue. It came when it appeared the bill was vulnerable in the House Rules Committee. The first committee vote had been six to six. This would have meant that the bill would not have been reported out and that it would have been dead for that

session of the 87th Congress. When this vote was announced, Representative Harris, co-author of the bill, advised the Rules Committee that the PMA supported the bill. On that basis two votes in the Committee changed, a rule was granted, and the bill went to the House floor and on to enactment.

Does this background impart special meaning to the legal actions which industry has brought to challenge the validity of two of the many restrictive regulations which the FDA has issued under the 1962 Amendments? Some persons regard our pending lawsuits as part of a continuing smoldering war between industry and the FDA. We do not. They see in these suits animosity toward government. We do not. As responsible citizens of this great country, we believe we have both the right and the duty to contest any regulation of the FDA which, in our legal judgment, is invalid because it exceeds the bounds of statutory authority. After all, ours is a government of law, not of men. The laws of this nation are designed to enable anyone to go to the courts to protect his constitutional rights when he believes that they are endangered or have been violated. This we have done as have other citizens and other industries. These suits then were instituted to get the courts to decide what certain language in this new law means. We and the FDA are having honest differences of opinion.

Challenged Regulations

A brief comment on the two lawsuits. The first case, filed in Federal District Court in Wilmington, Delaware on September 5, 1963, by the PMA and 37 member firms, challenged the statutory authority of the FDA to require by regulation that the generic or established name of a drug be repeated each time the proprietary or brand name is used in an advertisement or in labeling. We received a favorable decision in this case in April, 1964. It was appealed by the Government to the Third Circuit and oral arguments were made in April of this year. Last month, that court gave the government a favorable decision although on a procedural question which did not reach the merits of the case. Industry will carry the Third Circuit decision to the Supreme Court.

The other suit, which was filed in Wilmington on July 26, 1964, by the PMA and 41 member companies, seeks judicial agreement that FDA lacks statutory authority for its attempt to require extensive records, reports, and supporting data on "old" drugs which are "generally recognized as safe and effective," which have been exten-

sively used for long periods of time and which we believe are protected by the "grandfather provision" of the 1962 Amendments. Oral argument in this case is being deferred until the "generic-each-time" case is settled. In the meantime, the regulations are voluntarily being held in abeyance by FDA with respect to an agreed list of "old drugs."

These challenged regulations are, of course, not the only ones the FDA has issued under the 1962 Amendments. There have been quite a few others. As to these, we have formally submitted our comments, protests, and amendment. Some differences have been resolved, as was the case with certain portions of the advertising regulations where clarification and amendment were obtained through means of a public hearing. Others haven't been. But before deciding what can or should be done on these, it was felt that a reasonable period would provide the necessary experience and insight on which to base a sound decision.

There is a side to the matter of disputing FDA's interpretation of the law that is worth considering since it reflects how seriously the pharmaceutical industry viewed these suits before bringing them. For the preceding quarter century, there had been almost no litigation involving FDA decisions in applying the law. To break with the past was not an easy decision. And it was done only after industry had become convinced that the FDA's interpretations went far beyond the intent of Congress, not to mention the necessities of the public interest. In essence, therefore, the regulations issued under the Amendments have been more disturbing than the Amendments themselves.

Effects of the Drug Amendments

What has happened in the three years since the passage of the new Drug Amendments? They have contributed to a steady decline in the introduction of new drugs and have increased greatly their development and production costs. In 1959, the introduction of new, single, chemical entities in the United States' prescription drug market reached a high of 63. By 1963 this number had dwindled off to 18 and by 1964 to 17. And this while industry had substantially increased its research and development expenditures.

This year for the first time since 1959, an increase in the number of new products introduced over a preceding year has happened, as 18 (as of October 1, 1965) have been approved.

Data concerning the submission of new drug applications is much the same. In fiscal year 1959, 369 were submitted and 230 approved; in fiscal year 1963, 179 and 67; in fiscal year 1964, 160 and 84; and in fiscal year 1965, 203 and 53.

Like gold and tourists a considerable amount of research is going abroad. In part, this results from increased federal controls. Advantages to be gained also motivate this move. Firms are finding that some foreign governments are geared to act more swiftly on approvals of new products than is the United States. Consequently, people in these countries are benefitting from new discoveries before they become available here.

When the 1962 Amendments passed, everyone knew that industry and government would go through a period of readjustment. The only question was "How long?" Certainly, the FDA has not had an easy time administering these new amendments, particularly the new drug section. And no one has said that it has. But one obvious reason for fewer new products, and some of the other consequences I have mentioned, has been the tremendous increase in the amount of paperwork to be prepared by drug manufacturers and read by FDA scientists. The documentation under the new drug procedures has been so great as to seem at times to be unrealistic. It has proven to be a real hardship to scientists everywhere, in and out of industry, and it explains in part why the FDA has itself been weighted down under the burden.

All of us are aware of the costs in human suffering involved in time lags. But no one should be more aware of it than the Department of Health, Education, and Welfare which, some time ago, published a booklet entitled *"The Costly Time Lag Between Discovery and Use of Medical Knowledge."* The drug that is not there when needed may be a greater tragedy than the one which had some unfavorable reactions. The FDA will always have the awesome responsibility of weighing the possible harmful effects of a new drug against the good that it can do. And it must always make its decision with the discomforting knowledge that there isn't any such thing as absolute safety. In the highly volatile atmosphere of the last three years, this judgment has been made all the harder because of the political "second-guessing" which has become so popular in Washington. But in all of this, the public interest must be safeguarded, and it won't be if the reasons for forestalling decision are based on political or technical objections.

Some observers have suggested that the 1962 Amendments have brought all drug products to the same level of quality and reliability regardless of their costs. This is not the case nor was it the intent of Congress. The Food, Drug and Cosmetic Act is a consumer protection measure in the public health sense. It was never intended to be an economic lever. It can never regulate the sameness of quality into all drugs, no more than a university can graduate all its students with the same grades, same intelligence, and same ambitions. People differ in their drive to achieve excellence, and this is true of a drug manufacturer as it is true of any other manufacturer or person.

Some of the regulatory efforts of the last three years have entailed a profusion of paperwork requirements. This in turn has forced the FDA to bathe in a bottomless pool of minutiae, causing it to deal too much with the shadows and not enough with the substance of real problems. Many administrative-delay problems can be corrected or substantially minimized by delegating back to industry areas of responsibility where industry should be called upon to police itself. Such delegation would involve no lessening of strict industry accountability and no impairment of the public health. Is it unreasonable to complain that where only a few years ago it took an average of less than three months to get a new drug approved, it has taken an average of 18 months since October, 1962 to do so?

There is a wealth of industry expertise available to the FDA just for the asking. Immodestly, perhaps, but yet industry feels that all experts are not in government, and that it, too, can contribute to good government, good administration and sound enforcement of the nation's drug laws. This thought may awaken, and it should, memories of the climate that existed prior to the unfortunate Kendall Report. It would be a forward step to go back to some of the practices of those days when great reliance on voluntary compliance, consultation, and education highlighted the fine relationship existing between the regulated industries and the FDA.

New Drug Applications

No one is suggesting that the FDA should not have adequate time to review New Drug Applications (NDAs). But it is not unfair to say that some paperwork demands and some interpretative decisions have added unnecessarily to FDA's own burdens. It regards many drugs to be "new drugs" contrary to the intent of Congress. It requires duplicate bibliographical data and information on manu-

facturing processes and other matters which have little or no relevancy to the safety and efficacy of drugs. It reinstates New Drug status on almost any change in the labeling or composition of a drug.

But despite the concerns that have existed over the past three years, both in government and in industry, about the Drug Amendments of 1962, their interpretation and administration, a start has been made to find less cumbersome ways for the FDA to develop a sound judgment of a new drug's safety and effectiveness than is done at present. Industry has cooperated wholeheartedly with government in trying to work out a new format for NDAs. We believe a good solution has been devised. It includes the submission of a summary of the clinical part of the NDA, enabling FDA to make an initial review rapidly, and it will enable the reviewing officer to ascertain if all important details have been included and to obtain a general impression of the new drug and the NDA itself without going through thousands of pages.

Deficiencies in the NDA will, we hope, be called to the attention of the company by prompt communication. In the past, a sponsor frequently did not learn for six months whether or not his NDA was deficient or incomplete. Now he will learn promptly if anything is wrong with his NDA and will be able to take immediate steps to correct it.

This constructive approach and others of like purpose will in time have the effect of speeding up the introduction of new drugs, and making them more quickly and readily available to the American people. This is progress. It shows that the FDA and industry are adjusting to the requirements of the 1962 Amendments, and are working together. More frequent conferences, symposium type, if you will, are needed to discuss joint problems. More consultation and discussion should be had on the regulations prior to their issuance. In fact, more of everything that will improve the administration and enforcement of the FDC Act, and industry's understanding and compliance.

Industry, like the FDA, exists to serve the people. Industry welcomes cooperation with the FDA in every way possible. Industry, as does the FDA, wants to make the 1962 Drug Amendments work well, work effectively and work practically. We look forward to the next three years. **[The End.]**

Progress in Research—A Question

By ROBERT W. BALLARD, M.D.

Dr. Ballard Is Vice President and Director of Medical Research at Winthrop Laboratories, New York City.

IN 1962 CONGRESS PASSED THE KEFAUVER-HARRIS AMENDMENTS to the Federal Food, Drug and Cosmetic Act. The Food and Drug Administration (FDA) issued the regulations that pertain to these amendments in August 1963.

Briefly stated, these regulations covered six major categories that directly affect the scope and character of research on drugs for which the pharmaceutical industry is responsible. These six areas are:

1. Proof of efficacy for the intended use of the drug.
2. Controls on the distribution and use of investigational drugs.
3. Stronger requirements for approval or withdrawal of new drug applications.
4. Surveillance and record keeping of experience on approved drugs.
5. Control of drug advertising.
6. Principles for good manufacturing practices.

The Efficacy Requirement

How have these affected research on drugs? First, let us consider the efficacy requirement. Proof of effectiveness with many products is fairly easy and straightforward. Double blind trials are not needed, and are indeed dangerous with some drugs, especially the life-saving situations of the antibiotics, or the antihypertensives when used in hypertensive crises, but when you get over into symptomatic type drugs and behavioral effects, then laboratory tests cannot be the controls and it is necessary to utilize the blind type of trial. Unfortunately, the blind technique has now been so overstressed that we find medical journals unwilling to accept articles on drugs for

publication unless double blinds are in evidence, even when not needed. By the same token, many companies have been faced with the same reaction from various people at FDA.

Double blind, randomized, and cross-over type studies are extremely useful, but very time-consuming for both manufacturer and investigator, and also expensive. For the first time many companies are now using and hiring biostatisticians to help design the protocols and aid in the methodology of many trials. This is healthy, and a good result of the regulations. If anybody should know the pitfalls and drawbacks of a given drug, the sponsor or manufacturer should first. But all this has caused a minor upheaval in clinical research. Company statisticians disagree with outside investigators or their statisticians, or vice versa. Many good investigators just will not study a drug as specified by company protocol, so there ensues a period of discussion and eventually a compromise, or a search for new investigators. This again is time-consuming, expensive, and slows down research. Some prominent and capable investigators refuse to do placebo controlled blind tests on patients, and some even shy away from positive controlled trials. The bright spot in all this, however, is that there are enough competent and well-trained investigators being developed to enter into this kind of trial.

I would like to state at this point that presently the requirement is straight efficacy and not relative efficacy. I sincerely hope that this is the way it stays, because if relative efficacy was a requirement, the public would be deprived of many useful drugs. Individual variations in effect can be misleading, and a given drug can be more effective than any other in a few people, but perhaps not in the majority. Therefore, it would be criminal to withhold this drug from the few because the over-all results show it to be not quite as good as another. I purposely brought this up because we in industry, from time to time, hear talk that relative efficacy may eventually become a requirement.

Controls on the Distribution and Use of Investigational Drugs

The second area covered by the regulations concerns the control and distribution of investigational drugs. In the past three years I have witnessed a great expansion in the number of people required to handle all phases of drug information, particularly investigational drugs. In my own company we have had a 400% increase

in personnel for the investigational drugs in clinical research. We still need more. The FDA is also faced with the same problem.

The legal obligations of the sponsoring manufacturer call for careful records of distribution and retrieval of a new drug when the investigation is concluded. A similar duty is imposed on the clinical investigator. The status of an investigational drug must continually be borne in mind; the exemption that permits its use in clinical trials is terminated upon approval of a new drug application. All materials used in clinical investigations must be accounted for by both sponsor and investigator. This type of inventory control has caused some potential investigators to refuse to do drug trials. However, this reaction is not too common, but in some cases it has caused delay until a new investigator who was both capable and willing could be found.

Another phase of the control regulations on investigational drugs that has caused concern, particularly on the part of the investigator, is patient consent. In the beginning there was a great deal of misunderstanding and confusion here, but this is easing off. We still, however, get requests for individual indemnification agreements, liability policies, or some statement in writing that in the event of legal action as a result of the experimental drug, the sponsor will assume its share of the liability and stand behind the investigator. Patient consent has been part of medical ethics for generations, but this is the first time it is essentially part of the law of the land, and as such is distasteful to some investigators. As a result, we have seen some investigators refuse to enter into trials.

Stronger Requirements for Approval or Withdrawal of New Drug Applications

The third category is stronger requirements for approval or withdrawal of new drug applications (NDAs). Some six years ago I participated in the evaluation of a new phenothiazine that was approved in 81 days, with a total of 350 well documented cases. That number of cases would not now be adequate, nor would a drug be approved 81 days after submission. I cannot argue with the need for more cases nor the increased time requirement, but I can argue with the need for *more* than 180 days, and the requirement of many thousands of cases for an NDA. Unfortunately, this happens all too frequently, and because of the regulations requiring periodic reporting, if an NDA is delayed up to the reporting date, new material

comes in and the 180-day clock starts all over again. This further extends expensive research that frequently is repetitious and gains nothing that could not be proved with Phase IV studies while the drug is marketed. Just the term investigational or experimental puts the cost of a study up. Many doctors are willing to do good studies for nothing on a drug that is marketed, but not on an experimental drug. This I cannot call progress. From the industry standpoint it seems foolish to hold up a drug for minor chemical and animal information, if the clinical evidence of safety and efficacy is obvious. It is our hope that this will improve.

The fourth category is surveillance and record keeping of experience on approved drugs. This is necessary from both industry and FDA viewpoints. All new drugs should have continuous studies for the first several years they are on the market. This is progress, and represents no strain for industry.

Control of Drug Advertising

The fifth item is control of drug advertising. Good, sound medical facts are what drug manufacturers are after when research is done on their drugs. Most reputable companies present the facts truthfully and are honestly trying to be helpful to both patient and physician. However, the great emphasis on side effects is overwhelming all of us, including the FDA.

The adverse reaction reporting program is off to a fair start and should get better, but concentration on side effects has put too much information into the hands of the laity and the uninformed, who tend to misinterpret. As a consequence, more side effects are being reported now that aren't really side effects, but rather the imaginations of those who got their hands on medical advertising or package inserts. It is the duty of the manufacturers to provide all the information to the physician about the drugs they make. All side effects should be clearly spelled out for him, but they should not be emphasized over and above the therapeutic activity.

To wax theoretical for a moment, I would hate to be introducing digitalis as a new drug today. Anyone reading the toxicity and side effects would never use it in the present climate. However, digitalis

has been with us long enough now that the toxicity and side effects have taken their proper place. They are there, to be sure, but not as prominently as the therapeutic effect.

We have found in our studies that when side effects are listed on case report forms we get many more reported than if we just leave blank spaces and ask the investigator to put in the side effects. This is true even in double blind studies.

The sixth item is the principle of good manufacturing practices. While a drug is in the investigational stages it is repeatedly checked for stability and is frequently assayed. The procedures are by now automatic and routine, but the individual tests for assay may be changed as a further check. These techniques do not materially alter the course of drug research, except if there is a stability problem.

Conclusion

In conclusion I can say that progress is being made as a result of the 1962 new drug amendments. Some of this progress is a result of the new law. We are as concerned with the public health and safety as the FDA—in fact, more so—since our very existence is at stake. I must hasten to add, however, that in some areas progress is being delayed. Controlled drug trials are much more frequent and numerous than just a few years ago. This is real progress. The increase in the number of studies, the overemphasis of some aspects of drug testing, and academic nit-picking on minor items causes delay, expense to the manufacturer, and higher cost to the patient. This part is not progress, but signs of improvement are in sight. The industry has cooperated with the FDA recently, through the Pharmaceutical Manufacturers Association (PMA) Medical Section, in arriving at a workable certified summary for the NDA. Both the industry and FDA are catching up on their backlogs as a result of the new regulations. Both the FDA and industry should strive for a better public attitude about drugs. I would include Congress here, in the term public. Better and more progressive research on statistically significant numbers of patients can help point the way to more accurate and concise information about drugs. **[The End.]**

An Appraisal of Progress in Drug Marketing

By ANTHONY T. BUATTI

Mr. Buatti Is Chairman of the Pharmacy Administration, St. John's University, College of Pharmacy.

IN ORDER TO DISCUSS THE WAYS in which the pharmaceutical industry has developed greater safeguards in marketing in recent years, both in cooperation with the Food and Drug Administration (FDA) and independently, it is essential to examine its role, objectives, and responsibility.

The Pharmacy Industry's Functions

Mr. John T. Connor, Secretary of Commerce, in a paper presented at the Johns Hopkins University Conference in 1963, listed three major functions of the pharmacy industry: (1) "discovery and development of new drugs and biologicals to alleviate pain and to control and cure disease," (sometimes referred to as the research and development phase); (2) "translation of these developments as quickly and safely as possible into useful tools of medicine in the hands of the practicing physician" (essentially the marketing operations); and (3) "production and distribution of existing medicinal products that are safe and effective."

Quite aptly this statement expresses the raison d'etre of the pharmaceutical industry as a socio-economic entity. In general terms, these functions apply as well to the companies that produce proprietary medications. It further serves to explain the responsibility of the pharmaceutical manufacturer to the consumer and adherence to government regulations governing its production, promotion and sale of products.

However, the pharmaceutical corporation also functions in a free-enterprise system and is necessarily organized and operated to pro-

duce a profit. Thus it satisfies its responsibility to the people it employs and the stockholders that own it. It would be impossible to discuss the progress this industry has achieved without examining the underlying factors that affect the efficient functioning of the pharmaceutical corporation. The pharmaceutical corporation's relations revolves about three groups—the consumer, employees and stockholders, and the government. The marketing mechanism of each company is of vital importance to each of these groups. For the consumer, it speeds, distributes and makes available at a fair price and with a good conscience, its product which plays a significant role in public health. For the employees it provides gainful employment, which develops profits for the manufacturer that creates the capital for new research and development and the dividends for the stockholders. As for the government, in a sense, it sets the rules of the game. By its determination legislatively, of the proper procedures in research, development and marketing, it seeks to enhance the nation's health armamentarium as well as its economy.

Selling pharmaceutical products has one clear-cut purpose: the conduct of business for optimum profit. The continued growth of any corporation depends on its ability to maintain a fairly continuous profit structure. It must function in this manner in order to survive in a free-enterprise environment.

The successful attainment of this objective is interestingly reflected in a forecast of ethical pharmaceutical products that appeared in *Modern Medicine Topics* of January 1957. Ethical pharmaceuticals in manufacturers' sales dollars for 1954 were $959,224,000. The forecast for 1966 indicated an increase in sales of about twenty percent, or $1,150,000. This was compared to a population increase of thirty percent, or 192,500,000 for the same period. The forecast was far more accurate in estimating population growth. Last year's sales were approximately three billion dollars, surpassing by far the most optimistic expectations. The marked growth performance of the entire drug industry as compared with all manufacturing is primarily due to the growth of the ethical products. Between 1939 and 1963 the increase in shipments of proprietaries has been less than one-third as large as the ethicals.[1]

Profits maintained a high level throughout this period, as evidenced by the curious interest it aroused in various government

[1] Bachman, S. "Economics of Proprietary Drugs," *Annals of the N. Y. Academy of Sciences*, Vol. 120, Art. 2, N. Y., July 14. 1965, p. 877.

bodies in the last several years. It can safely be said that an industry, whose freedom of action has come under increasing scrutiny by the consumer, the government, and the medical professions, and therefore has been gradually restricted in its practices, has managed to fulfill its growth and profit goals. Under these circumstances, the growth of the industry to some degree is a measure of its efficiency in marketing many products that apparently were not only desired, but useful and safe. To this end, the goals of the corporation that pertain to the employees and stockholders have achieved success.

A proper evaluation of the successful marketing of drug products by the pharmaceutical industry is necessarily couched in its social responsibility. Each segment of society has a different yet important relationship to the corporation and its professional managers. Decision-making by management has become a complex process with both profits and social responsibility playing important parts. This refers to the moral responsibility of providing the medical professions and the consuming public with safe and effective medication.

Past experience indicates that the ethical pharmaceutical industry assumed its products were effective and created devious means to insure product safety. Today pharmaceutical products are very potent and many are very effective. Although specific in purpose, they also have a multiplicity of actions which are not necessarily desirable. Future marketing programs for both the ethical and the proprietary drug manufacturer will have to concern itself with relative effectiveness. The majority of pharmaceutical concerns are to be congratulated. They have consistently adhered to the goals of producing a better, safer, more effective product. In the long run this objective produces the profits desired.

Recent legislation pinpointing effectiveness as well as safety will have several effects on the marketing of pharmaceuticals. Many over-the-counter products which were of unquestionable safety, but questionable efficacy, will most probably gradually pass from the scene. The benefit to the consumer will be great in terms of increasingly effective drugs, with far more information for making an intelligent choice.

The negative phase of marketing is obsolescence which reached phenomenal proportions in the last decade. An average of about four hundred new drugs or combinations came on the scene each year, to compete with or replace a large number of products from previous years. The number of new single chemicals marketed has decreased

from sixty-three in 1959 to seventeen in 1964. More important, the total number of new products marketed has declined from three hundred and fifteen in 1959 to one hundred and sixty-two in 1964.[2] Although some have attributed this decrease to the complexity of government regulation, it is hoped that greater selectivity has been exerted in the light of increased sophistication on the part of consumers, the professions and the public agencies.

The tremendous economic impact of the specific and effective drugs of the past thirty years is hardly appreciated. Countless man hours have been contributed to reach production goals that have elevated our nation to the heights of the "haves" in world economy. Therefore as the public, along with government and industry, screens drugs for effectiveness and withdraws support from the ineffectives, a greater economy in medical expenditure will be realized.

The need to authenticate claims on drug products will remove a large number of fringe products from the market, or limit their claims, thus giving them an unprofitable share of the market. More importantly, it will prevent the further introduction of such products. The retardation of obsolescence will benefit the manufacturer as well as the consumer. The competitive frenzy to achieve market position, or domination by simply duplicating a successful product can be replaced by a determination to innovate, to create the new, the better, and needed product. The brakes applied to this disastrous trend will prove efficacious to the future marketing and product plans of the industry.

Genericism

The trade-mark and generic-name issue can seriously affect the continued creation of safer and more effective drugs. There is a place for generic-name drugs in the practice of medicine. It is also essential that manufacturers have the right to use trade-marks. It is the only way that a reputable firm can identify itself with its own quality products. Robert Parker stated in the October 25th *FDC Reports* that prescriptions for generic tetracyclines may account for 32-36% of the total tetracycline prescriptions written. The implication is crystal clear. The danger of genericism lies in two areas. The producers of generic products, for the most part, do little if any research in terms of new and better products. Their forte is to benefit

[2] Data prepared by Paul de Haen, N. Y. C., Pharmaceutical Consultant.

price-wise from the competition with trade-marked products, while assuming little risk in identity and a small, mainly distributive, cost. Hundreds of products are marketed which have limited use, but are as essential as any of the glamour pharmaceuticals. Generic-name products, if not dealt with in competitive terms by the reputable firms, can seriously affect the future health of the American people.

Many sectors in our economy, as well as the general public, have come to believe that generic equivalent equates chemical equivalent or pharmacologic equivalent with clinically effective equivalents. Three doctors recently presented an article in the February issue of *American Professional Pharmacist,* in which they listed twenty-four factors that markedly alter the pharmacologic action of a drug.[3] It is inconceivable that the American people are willing to sacrifice health and well-being in order to spend less, while demanding and paying for quality in many less important commodities. These three doctors stated:

> It is practically impossible for one not skilled in the area of clinical pharmacology to know what is—and what is not—a real "equivalent." . . . Our conclusion is that generic equivalency is frequently a fable without basis in fact; chemical equivalency of the primary agent or agents is not necessarily clinical nor pharmacologic equivalency.

Education

Both the proprietary and ethical pharmaceutical manufacturers have taken great strides in adhering to the letter of the law in their promotional efforts. Over-the-counter and new ethical drugs are presented only as stable, safe and optimally effective dosage forms. The spirit of the law is of some concern, however, and therefore a secondary, extremely important aspect of promotion is education. The consumer who self-medicates himself, and the medical practitioner who prescribes must be thoroughly and completely informed on all the specifics of proper usage, proper dosage, administration and whatever cautionary advice is relevant. Practices such as market selectivity or restricted circulation of samples and product information, result in only a segment of the medical practitioners' being thoroughly and completely informed on existing and new products. All other physicians are left to receive the promotional presentations second-hand, or not at all. The physician may fail to receive much of the pertinent data on side-effects, cautions and precautions, in administering the medication.

---

[3] Sadove, M.S., M.D; Rosenberg, R., M.D.; Heller, F., M.D. "What Is A Generic Equivalent," *American Professional Pharmacist,* February 1965.

Inadequacy of training or of previous educational background of the medical service representatives, or the exaggerated emphasis on selling as opposed to informing and educating, will prove harmful. Recognition of these important factors in promotion by top executives is sometimes distorted by an inept or not-too-well-defined channel of communication from the top executives to the field force.

An example of the aforementioned practices is the medical service representative who attempted to increase the sales of one company's codeine-containing cough preparation by indicating to the pharmacists that teen-agers and young adults were buying the cough medicine for illegal purposes. The company's recognition of the problem of addiction among this age group was obvious—a new product was released containing a non-addicting cough depressant. A medical representative of this caliber does great harm to the company's image, as well as creating the impression that his selling tactic is company policy.

Efforts for Self-Regulation

There are many examples of the pharmaceutical industry's efforts in self-regulation. The most recent is the new concept in drug manufacturing initiated by Merck Sharp and Dohme when they installed an adaptation of the "Zero Defects" program. Throughout the years voluntary compliance by the industry has effectively reduced the government's role in enforcement and compliance with the food and drug laws.

A quick look at a social history of American drug legislation does show a trend which is disturbing. The very first efforts to obtain legislation to rid the industry of unscrupulous individuals or companies were initiated by the sincere, reputable pharmaceutical manufacturers and consumer groups. As the laws became more stringent the consumer groups, political groups, and finally the legislative branch of government have played more central roles in obtaining restrictive laws. The industry has lagged somewhat, self-regulation being replaced with federal enforcement.

A high degree of freedom of action of this essential, growing industry has to continue. Increasing government control is undesirable, yet if the industry does not re-establish its self-imposed restrictions, it will be faced with ever-increasing and research-retarding legislation. The consumer will suffer most, because better and safer drugs will take so much longer to reach the market place. An in-

teresting legal issue of government-imposed safety and effectiveness measures is the problem of liability. The federal government and the manufacturer might both be held liable if a new drug does not live up to its licensed indicated performance.

The burden placed on manufacturers in their advertising on product leaflets, of putting in reams of cautionary material can be obviated. Unless some important overlying health objective is to be served, pharmaceutical products which require so much information on side-effects, cautions, precautions and warnings, perhaps ought not to be marketed. Two months ago a product was released on the market. The accompanying leaflet contained three pages explaining why and how the product should be used, and nine pages on why it should not. The average physician would find it difficult to administer this product with any degree of assurance.

The highly improved educational background of the recently graduated pharmacists, and the expansion in facilities and faculties of the colleges of pharmacy, can play an important role in improving the marketing practices. The profession of pharmacy is ready and willing to provide greater know-how in research and development, marketing management and market research, and the manpower.

The colleges of pharmacy have shown their desire to cooperate with industry in bringing all the forces to bear for the improvement of health through their programs of continuing education. At St. John's University, for instance, there have been seminars in Pharmaceutical Aerosol Technology, Pharmaceutical Detailing and the Law, an Annual Pharmacy Congress, and Postgraduate Medical Technology. Programs of this nature are available in several sections of the country. Industry cooperation and participation has been excellent. All means for the exchange of ideas to improve the practice of pharmacy in industry and professionally should be scrupulously explored.

The people of the United States and of the rest of the world deserve the best in medication and medical and pharmaceutical practice, supplied as economically as possible. It is up to the pharmaceutical industry, operating in a free-enterprise system to continue to demonstrate its superiority in doing so. **[The End]**

Congressional Investigations: Some Observations

By WILLIAM C. WARREN

Mr. Warren Is Dean of the Law School, Columbia University.

THE POWER TO INVESTIGATE is probably the most important single factor which has gained for both the British Parliament and the Congress of the United States a stature which their Continental counterparts have never achieved. The Congressional authority to investigate the activities of the Executive is our legacy from British constitutional practice and is an essential part of the system of checks and balances which has been so important throughout history to the preservation of our democratic form of government.

Roots of Government Investigation

The roots of government investigation reach deeply into our legal origins. We learn that soon after the Norman conquest of England in 1066, William the Conqueror sent Royal Commissioners into every county of the kingdom to ascertain the ownership of each estate in land and to determine its value for purposes of taxation. These founders of our legal traditions were evidently more frank and uninhibited than today's tax gatherers, for they called the resulting compilation of property and tax evaluations, appropriately enough, the "Doomsday Book." King William I and his successors made frequent use of such investigations to learn the facts concerning the kingdom—facts without which efficient government is impossible in any age.

In the course of the fourteenth century, with the rise in the influence of Parliament, we find the beginnings of a rivalry which has continued to the present day, not only in England, but also in the United States. I refer to the never-ending contest for power and influence between the Legislature and the Executive. As Parliamentary

strength increased, Parliament appointed its own investigating bodies, while at the same time the investigating function of the Crown was curtailed. In periods when strong or self-willed kings were able to overbear more timid Parliaments, as was the case during the Tudor and early Stuart reigns, the functions of the Crown were expanded at the expense of the Parliament, and Royal Commissions again became important fact-finding agencies for the Executive. When the Parliamentary Party finally prevailed in the civil war which cost Charles I his head, most of the important Royal Commissions were abolished, in reaction against their abuse by the Stuarts and Tudors, and the Parliamentary inquiry once more became the primary organ for governmental fact-finding.

The British House of Commons held its first formal legislative investigation in 1571, almost four hundred years ago. Then, as now, elections sometimes resulted in charges of fraud, and the charges were serious enough in 1571 to warrant a parliamentary investigation into the facts. The results of that particular investigation are no longer important, of course; what is important is that the legislative investigation device continued in use in England down to the time when the American colonies were established. The colonists therefore assumed, without question, their right to inquire into the conduct of their officials, as well as into other matters of general concern.

For example, in 1691 the New York Assembly, informed that a certain Reverend Daillé had prepared a petition and had it signed by inhabitants of Harlem and Westchester, summoned him to appear before the House. Upon his refusal to answer the questions put to him, he was declared guilty of contempt and committed "to the custody of the Sergeant at Arms, and there to remain until he shall make answer, or be discharged by the House." Legislative methods have changed very little; the citation for contempt, although such a charge is now tried in a federal court, is still the principal device used to compel testimony from witnesses before Congressional investigating committees.

During the Indian War in 1722, the Massachusetts House of Representatives called before it two militia officers, Colonel Walton and Major Moody, to inquire into their failure to carry out certain offensive operations against the Indians. The House insisted that it was "not only their privilege but Duty to demand of any Officer in the pay and service of the Government an account of his Management while in the Public Employ." The parallel to the Joint Congressional investigation into the conduct of the military and naval

commanders in Hawaii after the attack on Pearl Harbor, over two hundred years later, is obvious.

Time does not permit us to explore such vignettes at great length, but examples could be multiplied, and history makes it clear that the power to conduct investigations into Executive conduct was, from earliest time in America, considered to be a necessary adjunct to the legislative authority. It should not be surprising, therefore, that one of the early activities of the newly-established United States Congress was an investigation, in 1792, into the conduct of a military officer, Major General St. Clair, who was alleged to have failed in his campaign against hostile Indians, nor is it surprising that the authority of the House to conduct this investigation was never questioned.

Congress' Right to Compel Testimony

While there was from the beginning no dispute over Congress' power to investigate administrative or Executive conduct, however, there were clear differences of opinion as to Congress' right to compel testimony in order to obtain information regarding the necessity for, or to aid in, the enactment of legislation, and it was not until the late nineteenth century that the House, by a closely-divided vote, vested in one of its committees the power to require witnesses to testify in a "law-making" investigation. By finally conceding the necessity to conduct inquiries with a view to legislation, the Congress implicitly recognized that no legislator or group of legislators could possibly know enough about the complex world in which we live to devise appropriate statutory solutions to the nation's problems without the enlightenment to be derived from thorough investigation.

Today, in a more sophisticated society than that which existed a century ago, it is commonly accepted that fact-gathering is often a necessary prior condition to the enactment of statutes, and that, in order to be able to obtain the necessary facts, Congress must have the power to compel testimony. The road to clear and undisputed Congressional investigative authority has not been entirely smooth, however. For nearly a century after its inception, the Congressional authority to investigate was strengthened by repeated exercise, and was subject to little or no control by the courts. In 1880, however, the Supreme Court sharply limited the power in the case of *Kilbourne v. Thompson,* 103 U. S. 168 (1880), denying that the House had a general power to punish for contempt, and requiring that any Congressional investigation in which testimony was to be compelled must have a clear constitutional purpose.

In spite of the doubt cast on Congressional powers by this case, Congress continued to investigate whenever it considered investigation necessary, and it is entirely possible that the obviously useful purposes served by the investigations of the corruption of the Grant Administration and, more importantly, of the Teapot Dome scandal during the Harding regime, and the consequent heightened public attention to and concern with such investigations, may have influenced the Supreme Court's next opinion on the subject. *McGrain v. Daugherty,* 273 U. S. 135 (1927), dispelled most of the doubts created by the *Kilbourne* case more than forty years earlier, and clearly recognized the Congressional right to investigate as part of its law-making function. It was not until 1947, however, in *United States v. Bryan,* 72 F. Supp. 58 (D. C. 1947), that a federal court supported Congress' right to compel testimony in any matter which might have the remotest relevancy to any possible legislation.

Shift in Policy-Making Initiative

Thus, the Congress is endowed with authority which is vitally necessary if that body is to perform the function for which it was designed in the formulation of national policy. Largely because Congress has failed in recent years to keep pace with the demand for enlightened national policies and programs, the initiative in policy-making has shifted almost entirely to the Executive. Indeed, when both the Congress and the Executive have been ineffective in this regard, perhaps because of a failure to inform themselves and the public, the courts have occupied the vacuum. The Congressional investigation is probably the sole means by which the Congress may begin to reassert its proper degree of control over national policy and perform its assigned function in our system of checks and balances.

Properly used, then, the Congressional investigation is a powerful tool in the hands of the Legislature. It permits the Legislature to insure that the laws are fully, fairly, and properly carried out by the Executive and his agents, it provides the means whereby the need for new legislation may be readily ascertained, and it is frequently useful, by influencing public opinion through exposure of the facts, in remedying wrongs and ending abuses without the necessity for statutory enactment.

In an era in which almost any human activity may have relevance to possible legislation, the fields of investigation opened to the Congress by the court decisions I have mentioned, and the opportunity for constructive use of this very practical tool, are almost unlimited.

The relatively unfettered power to investigate practically anything, under little or no external control, however, is a power particularly subject both to abuse and to criticism, in the context of our political system. For example, although Congressional investigations in the early days of the New Deal led to the economically beneficial Banking Acts of 1933 and 1935, the Securities Act of 1933 and the Securities and Exchange Act of 1934, the committee hearings themselves were severely criticized at the time. The manifest purpose of Congressional investigations in the latter part of the same Administration was to embarrass or restrain the Executive, and the motives of those who conducted the investigations were questioned, yet there are scholars who claim they served a useful purpose. Politically motivated investigations reached a peak unmatched before or since during the last two years of the Wilson Administration, when the majority of the Congress were of a different political party from the President's, and 51 Congressional investigations were going on simultaneously.

Investigations, therefore, may be politically motivated, their main purpose being the embarrassment of the Administration or the discrediting of a political party in order to achieve an election advantage. The publicity attendant upon investigations into matters of great public concern, moreover, provides a temptation almost irresistible to elected officials, for whom publicity is the best guarantee of re-election or higher political office, and there is good reason to believe that the hope for such publicity is frequently the operative factor in the initiation of an investigation.

Use of Advisory Committees

The very structure and organization of our government lend themselves readily to the proliferation of investigations—the system generates them. Congress has increasingly placed greater responsibilities on administrative agencies and delegated to them the authority to carry out the legislation with many of the details not spelled out. This has required the agencies to develop regulations that take on the character of "quasi-legislation." Every agency is certain to have difficulty here in trying to interpret and develop the appropriate rules and action. In resolving these and other difficult administrative problems, there seems to be emerging a pattern of administrative procedures that differs sharply from my own experience in government. I refer to what appears to be a tendency on the part of administrative agencies to refer to groups of private citizens on an *ad hoc* committee basis, for study or research and recommendation, problems which fall squarely

within the ambit of the agency's responsibility, and to which the agency is presumably equipped to apply its own acknowledged expertise. The increasing use of these advisory committees begins to take on an institutional character quite different from the use of consultants by an agency, even though they may be the same persons.

The most recent example of this tendency which has come to my attention is the announcement by the Food and Drug Administration (FDA) that it is delegating to an "advisory council" of scientists the task of accomplishing scientific studies in an area of prime importance to the Agency and of considerable interest to the public—and therefore to Congress.

It seems to me obvious that an administrator who receives a recommendation on a problem of this kind from a panel of distinguished experts is likely to adopt the recommendation as his decision, without the soul-searching critical analysis to which he would subject the same recommendation from his own official staff, even if that staff consisted of the very same experts. When he does this, he is, of course, in the comfortable position of being able to point to an authoritative report, submitted by presumably disinterested experts, in the event his decision should later prove to be ill considered, and his judgment and capability should be challenged by a Congressional investigating committee, but it is quite clear that by so doing he also abdicates his official function and deprives the Administration of the very qualities of expertise he was engaged to bring to his problem.

Conversely, it would require a very strong administrator indeed to make a decision contrary to the recommendation of such a panel; since again, if events should prove such a decision to have been ill-advised, the administrator's error is compounded by the fact that he made a decision different from that advised by a panel of his own selection. The danger of such double exposure to the scorn of a possible future investigating committee would act as an additional deterrent to an administrator's making a decision different from that which was recommended.

To me, these seem to be fairly cogent reasons for the administrative agency to use its own expertise. I fully appreciate the reason that they are not able to rely solely on their own expertise. This is because of the lack of funds. Presidential budget requests and Congressional appropriations determine the agency's ability to employ full-time experts required to accomplish the agency's mission. If the funds available are inadequate for retaining scientific expertise on an employee basis, the agency is compelled to engage part-time assistance

to do its job, either consultants or a group of advisors as an *ad hoc* advisory council or committee. I believe that we must watch closely the use of these *ad hoc* advisory councils because of the possible dangers that have been pointed out. The use of consultants would not seem to have the same pitfalls, although their use does not provide the same "window dressing."

Criticisms of Congressional Investigations

The principal criticisms of Congressional investigations are that, because of their freedom from external control, they can assume all the aspects of a trial without any of the safeguards which surround the individual under usual court procedure; that the legislators, who purport to act as judges, are also, in fact, prosecutors and jury; that the publicity deliberately courted by investigating legislators may expose witnesses to loss of employment or reputation, and other damage; that Congress itself refuses to impose procedural rules upon its investigative process; and that Constitutional guarantees are in fact violated by Congressional inquisitors.

It would be a sufficient reason for concern if these criticisms were based solely on the proposition that such abuses *could* occur in the procedural and political setting in which Congressional investigations are conducted. Unfortunately, experience has proved that all of these abuses do in fact occur under our system. The depressing spectacle of the McCarthy hearings and certain hearings of the House Un-American Activities Committee will long be with us; these and other investigations, apparently motivated by personal or political ambitions, have been characterized by irresponsible charges, violation of individual rights, the "smear" technique, the insidious assassination of character through the imputation of guilt by association, and other evils.

Such abuses have caused resentment, and properly so. The deep concern of responsible Bar Association Committees and other groups, communicated to the Congress, has resulted in the past in a spate of bills in both Houses aimed at the imposition of procedural rules which would protect the rights of individual witnesses who are the objects of Congressional inquiry. Invariably, all such attempts have died in Committee. Yet some Congressional Committees—and we may hope that these are establishing a pattern for the future—have adopted their own procedural rules to insure objectivity and fairness.

In addition to the legal shortcomings of a system of investigation in which legislators are both inquisitors and judges, one very practical

objection has been made to the work of Congressional investigating committees. It is bluntly put by critics that such committees are inefficient and incompetent; they simply cannot do the job. It is alleged that the task of investigating any of the complex activities of a modern government agency or business organization requires that many hours be spent in preliminary concentrated study of intricate detail. The demands on the time of a member of the Congress are such that he cannot possibly master the knowledge necessary to intelligent examination of witnesses. Consequently, Congressional inquiry is frequently inept, repetitious, and unproductive. The contention is not entirely without merit, for the critics can point to the recent and much-publicized "investigation" into Ku Klux Klan activities as a typical example of this wasteful aspect of the Congressional investigation.

Proposed Solutions

Solutions to the problem presented by the sad spectacle of those Congressional investigations which are unfair, lawless and inefficient have been proposed by various groups and individuals who have studied the problem. Perhaps the best known of these is a procedure modeled upon the highly successful Moreland Act of New York, which authorizes the Governor to appoint commissions to examine into the activities of any agency of the State. Commissioners so appointed have subpoena power, as well as authority to employ investigators and legal counsel, and their reports are submitted to the Governor for further submission to the Legislature. The Governor, realistically conscious of the political necessities, has usually appointed capable, objective, and reputable commissioners, with the result that, for the most part, the Legislature has been satisfied to restrain itself and await the reports of investigations carried out by men who have neither the need nor desire for publicity, and whose ability and dedication are unquestioned. If it is nevertheless considered that legislative hearings must thereafter be held, they may be held on the report itself.

Substantially the same system is employed in England, where, aside from the Royal Commission, the Tribunal of Inquiry is the device normally relied upon when investigation is necessary. Tribunals of Inquiry are authorized by the Legislature, but the Tribunal members are appointed by and report to the Executive. The administration furnishes the Tribunal with terms of reference, within the parameters of which the investigation is confined. Witnesses are entitled to counsel, who may cross-examine, and the Tribunal's conclusions are

supported by a detailed analysis of the evidence. The objectives of efficiency, fairness and objectivity are thus achieved. Such a concept is not likely to appeal to the Congress, however, for it does not always foster the political result which from the legislator's point of view, is a desirable auxiliary benefit to be derived from an investigation. More importantly, the use of what amounts to an Executive investigating commission, rather than a legislative committee, would deprive the Congress of its most important device for checking and balancing—that is, for restraining—the Executive, and for informing itself and the public of the facts which indicate the need for legislation.

Finally, there is a significant difference between the positions of the Executives in England and in the United States which may account for the acceptance of the Executive investigation by Parliament, and its unpalatability to Congress. Unlike the President, the British Prime Minister and the members of his Cabinet are also members of the House of Commons. The members of his party in Parliament therefore share with the administration a sense of full responsibility for all the Executive's acts and omissions. Under our own system, in which the Executive and the Legislature constitute separate branches of government, each designed to restrain the other, the result is quite different.

It is interesting to note, moreover, that even in England, where the governmental structure has traditionally provided a political atmosphere congenial to the use of the Executive investigation, public misgivings are now being expressed at the resulting failure of legislative control over the Executive and the lack of information, on the part of responsible legislators, on modern British society and its changing needs. *The Economist,* in the lead editorial in its most recent issue, deplores the consequent inefficiency in government, and suggests that the obvious remedy is "something on the lines of the American system of specialist committees."

It is therefore clear that Congress, traditionally distrustful of the Executive, must inevitably entertain grave reservations concerning the bona fides of any commissioner appointed by the President, and a bill was introduced in the Senate in 1950 in an effort to eliminate this factor and achieve consensus on a modified federal Moreland Act. The bill attempted to allay Congressional mistrust by authorizing the President to appoint a panel of thirty nongovernmental commissioners, subject to the advice and consent of the Senate. Thereafter, when it should become necessary to establish an investigating com-

mission, these Senate-screened appointees would be outnumbered on the commission, in the ratio of four to three, by members appointed from their respective Houses by the Speaker of the House and the President of the Senate. This effort was unsuccessful, and fortunately so, for entirely aside from the fact that a commission so large is too cumbersome to permit effective performance, the presence on the same commission of members representing both the Executive and the Legislature would hardly be likely to result in the kind of cooperative, purposeful work which is necessary to successful investigation.

Both history and recent experience, therefore, reinforced by constitutional and practical considerations, indicate clearly that the Congressional investigating committee will continue indefinitely to be the primary means by which the Congress will inform itself and the public of facts, opinions and prejudices—all necessary to the legislative function—and by which it may inquire into the activities of the Executive.

The Future of Congressional Investigations

In evaluating the probable future of Congressional investigations, a number of frequently competing interests must be carefully considered. The need of the public and of Congress to be fully informed, not only in matters relating to the conduct of Executive affairs and matters affecting legislation, but also quite broadly on national policy, posture and intentions; the need of the Executive to be free from petty harassment; the need of the private person, and, indeed, of the public official, to be protected in his Constitutional rights and to have a forum in which he can effectively meet Congressional attacks on his capacity, character and ability; these and other needs are not susceptible to easy accommodation.

As I have indicated, many, if not all, of the criticisms levelled at Congressional investigating committees are, in one way or another, based on fact. It does not follow, however, that because the facts alleged are true, they are necessarily bad. We should not be concerned, for example, over allegations that Congressional investigations frequently are "politically inspired." All Congressional investigations are "politically" motivated, in the broad sense of the word, just as all legislation is, and that is as it must be in a democracy. Using the word even in its narrowest and plainly derogatory sense, however, there have been many occasions in our history when exposure solely for the political purpose of exposure has had salutary effects. Such

occasions, we may be sure, will arise again, for the arenas of politics and commerce afford many opportunities for conduct which, while within the law and beyond the ambit of existing legal process, is nevertheless undesirable and not in the best interests of the country. In such cases, exposure for its own sake serves a valid and highly desirable purpose.

The critics allege that investigations are sometimes motivated by a desire for publicity. It seems to me perfectly obvious, however, that publicity and the hope for political reward are significant and useful stimuli in our political process. It becomes increasingly apparent, moreover, that the publicity which will produce political rewards must be of a kind which will generate confidence and respect on the part of a constantly better-informed electorate. This factor alone must eventually act as a deterrent to Congressional excesses and as a stimulant to legislators to perform creditably. That this process is already affecting the Congress is manifested by the fact that several Congressional committees have now adopted rules of procedure designed to insure that witnesses will be treated fairly and evidence gathered objectively.

Criticisms based on the claimed inefficiency of Congressional committees in the investigative area can be met effectively by increasing committee staffs and raising the level of their expertise. The relatively small increase thus occasioned in the cost of investigations would be more than compensated for by higher quality results and greater efficiency.

In any event, it is not necessary, in order to correct real or imagined deficiencies, to destroy or even to inhibit the vital Congressional power to investigate. Transfer of the investigating function to some other agency—always an attractive alternative to those dissatisfied with Congressional activity—would not only hamper the Congress and eventually jeopardize our freedom, but would serve no useful purpose. Experience has not shown that other groups are less likely than elected legislators to be prompted in their actions by parochial, selfish or venal desires, and few would care to argue that New York, employing the Moreland Act, is better governed than is the United States, using Congressional investigating committees.

Conclusion

We may confidently expect that the present trend toward Congressional self-discipline will continue, for the object-lesson of a

Senator destroyed by publicity of his own making, and by the public indignation which resulted from his irresponsible injury both to persons and to the image of the Congress, has not been lost upon its members. We may rely upon a steadily increasing measure of individual and collective Congressional restraint to restore to legislative investigations and investigators the dignity and public respect which they should properly enjoy and which the country has a right to demand they achieve. While progress in this direction has been slow in the past, this is probably because the Congress had never before seriously attempted to police itself, and because prior manifestations of the public's indignation at Congressional excesses have been, at best, sporadic. The public's new and continuing awareness of the sins which can be committed in the guise of investigation, however, and Congressional sensitivity to public reaction, will expedite the process.

By making continuing efforts to discharge the responsibility which clearly lies upon it, to insure that any investigation undertaken in its name is conducted objectively, without undue political bias and with scrupulous regard for individual rights, the Congress will be able to retain in its own hands the formidable tool which permits it to function effectively, and will eventually achieve a tradition which would characterize a McCarthy, not merely as a somewhat more-than-ordinarily irresponsible committeeman, but as a shocking aberration, to be dealt with promptly and with finality by a Congress incensed and outraged by un-Congressional behavior. **[The End]**

DR. JAMES L. GODDARD BECOMES NEW FDA COMMISSIONER

Dr. James L. Goddard, a forty-two-year-old assistant surgeon general of the United States Public Health Service, has been sworn in as Commissioner of the Food and Drug Administration to succeed George P. Larrick. The new Commissioner was the director of the Communicable Disease Center in Atlanta, Georgia, and had been with the Public Health Service for fifteen years.

Dr. Goddard is the first commissioner since 1921 to hold a medical doctor's degree, and is also the first in many years to be recruited from outside the FDA.

Food and Drug Administration Industry Information Programs

By HAROLD F. O'KEEFE

Mr. O'Keefe Is the Director of the Division of Industry Advice, Bureau of Education and Voluntary Compliance, Food and Drug Administration.

A BASIC, CONTINUING PROBLEM confronting both the regulated industries and the Food and Drug Administration (FDA) is the necessity for assuring ourselves that innovations in processing, packaging, and labeling of foods, drugs, and cosmetics are accompanied by controls adequate to insure that these consumer products are safe, and are truthfully and informatively labeled. In the industries which you represent, there has been such dynamic growth in volume, in variety of products, and in new processing and packaging methods that the need for such controls is a major challenge and obligation. To assist in every manner possible in meeting these challenges and obligations within the framework and purpose of the Food, Drug and Cosmetic Act is the prime objective of our industry information programs.

The importance of better communications between us and the regulated industry has been pointed up by two Citizens' Advisory Committees since 1955. Changes in the basic law, strengthening of regulations and improvements in scientific methodology have also pointed up the need for a more adequate and formalized communications system. In order to meet these new communication needs, we have created some specialized organizational units to supplement other expanded units that have long followed the "open door policy" of free and frank discussions with industry individuals and groups. Our new units are in an early stage of growth and development, looking forward to still further progress in the years to come, but we are proud of what we have done so far. I will tell you about some of these achievements which have evolved within the framework of the "Creed of the Food and Drug Administration" formulated by former Com-

missioner Paul B. Dunbar in 1947. I believe this truly represents the thinking of the FDA now as then.

We believe that the American consumer is entitled to pure, unadulterated, and honestly labeled foods, drugs, and cosmetics; that Congress in enacting the Food, Drug and Cosmetic Act had as its clear objective the principle of promoting "honesty and fair dealing in the interest of the consumer;" that, in the language of the Supreme Court, "the purposes of this legislation touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection;" and that Congress intended to carry the consumer-protective provisions of the statute to the limits of constitutional authority.

We believe that most American manufacturers of foods, drugs, and cosmetics have the scientific knowledge, the technical equipment, and the will to produce articles 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 the interest of industry; 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.

We believe that the Food and Drug Administration in enforcing the Food, Drug and Cosmetic Act must keep ever before it the purposes of Congress; that fairness and regard for these purposes should infuse every enforcement procedure; that when judicial interpretations indicate that the language of the statute does not effect the full purpose of Congress it is the duty of the Food and Drug Administration to recommend corrective amendments; and that it must 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 both of the consumer and the ethical manufacturer.

To me, this is a vibrant, living creed as applicable today as in 1947 because within its framework are encompassed the several important amendments to the law, the volumes of new regulations, and the scientific advances of the past several years. The purpose of our industry information programs is to help you comply with the law—that is, we want to make available to you a service, information, and, if possible, motivational measures which will prevent violations due to ignorance and negligence. For the deliberate violator, there is only one solution—conventional regulatory action. Here, too, I would like to emphasize that it is neither the purpose nor the function of our Bureau of Education and Voluntary Compliance to act as intervenor when you have been found violating the law. We want to help you prevent the illegal act.

Basis for the Programs

These informational activities are based on three well-established principles. The first is that the laws of this land are public laws and citizens are not to be harassed by secret regulations or secret pro-

ceedings in the courts. Regulation and standard-making is a public process—a recent example, peanut butter—and both the Federal Food, Drug and Cosmetic Act and the Administrative Procedure Act have spelled out the responsibilities of law enforcement agencies for public procedures.

The second is that intent to violate the Food, Drug and Cosmetic Act and the other laws we enforce does not have to be proved as an element of the offense, and ignorance of the law is no excuse. But the businessman also has reason to appreciate his responsibility under law, for the alternative is regimentation. Freedom and responsibility are two inseparable aspects of a government of laws.

However, the second principle as stated is considered in relation to the first. It becomes obvious that the enforcement agency has an added responsibility to see to it that one does not nullify the other. As a practical matter, this means that we must be able to demonstrate that the regulated industries collectively have been given every reasonable opportunity to know what the law and the regulations require. This is a great and growing responsibility. Much of the material which we issue—some of which I will describe in this talk—is designed to see that these two principles do not come in conflict; and there are many checks and balances in our system of government.

The third principle is especially applicable to laws that protect the public health and safety. We call this "preventive enforcement," which simply means activities designed to help industry comply with the law. To illustrate, it is of little consolation to the mother of a child that has been injured by a faulty or mislabeled drug to know that the manufacturer is subsequently prosecuted for inadequate manufacturing controls. Neither is the public adequately protected by seizure of a shipment of contaminated food after other shipments of the same product have already been consumed. Preventing any such shipment would have given far better protection.

Significant is the fact that the law itself has largely become a *preventive* rather than a *punitive* law. This movement began with the new drug provisions of the 1938 Act and continued at an accelerated pace through the Pesticide Chemicals Amendment of 1954, the Food Additives Amendment of 1958, the Color Additive Amendments of 1960, and the efficacy provisions for new drugs in the 1962 Drug Amendments. These amendments have firmly established the principle that manufacturers have a legal responsibility for determining the safety of their products before they are made available to the public. This is one of the great social ideas of our time. The procedure for

complying with these pre-marketing requirements is probably the greatest contributing factor to increased communications between industry and government, contributes importantly to mutual understanding, and has undoubtedly eliminated a great deal of litigation that might have otherwise been necessary to resolve questions of public safety and deception. Such a preventive law requires much interpretation as well as postings of "speed limits" and "Keep Off the Grass" signs. In addition to these, we think there is a need for more elaborate and formalized informational programs in other areas and have recently activated the Division of Industry Advice in the Bureau of Education and Voluntary Compliance and invested it with responsibility for broad programs in the industry area. We are a young, lightly staffed unit; we are in the early stage of growth and development; we are looking forward to still further progress in the years to come, and we take pride in what we are doing.

Organization of the Division of Industry Advice

The goal of the Division of Industry Advice is to apprise industry about the requirements of the law so that no one may honestly be able to say that he violated it because he couldn't find out what it required. Let me therefore describe our organizational setup and the roles of each unit very briefly.

The Drug, Device and Cosmetic Advisory Branch and the Food Advisory Branch provide assistance to members of industry to help them understand the various laws we enforce, and particularly to understand how these apply to specific products and processes. These branches offer free consultation and advice—in person, by telephone, or by mail—on compliance matters for any individual or firm requesting it. Labeling of products, suitability of ingredients, application of the law to particular situations—these are merely illustrative of the range of subject matter on which advisory branches are able to give helpful advice to manufacturers seeking to comply with the law. For example, during the last fiscal year, these branches handled approximately 15,000 written inquiries, 8,500 telephone inquiries, and 1,700 person-to-person interviews with industry representatives.

Opinions given by the advisory branches represent "institutional" decisions on the meaning of the law and regulations and their applicability to specific situations. These opinions, however, carry no legal authority and are not intended to serve as regulatory guidelines. We hope, however, that they will serve as practical aids and guidelines to the honest businessman who wishes to market clean, safe,

and honestly labeled products. We are not always able to answer all your questions promptly, for oftentimes we are asked for opinions that require consideration by members of our scientific and medical staff, policy makers, those responsible for regulations, our General Counsel, and sometimes other government agencies when the problem touches upon their area of responsibility. These take time.

The function of the Special Programs Branch is to develop special informational programs to help you understand the law and regulations and FDA policy. For example, it provides reprints of regulations and orders, prepares and makes available pamphlets, leaflets, and explanatory trade press releases, arranges for or furnishes speakers for industry meetings or workshops, and exhibits for conventions.

During fiscal year 1965 this branch distributed 337,000 copies of 30 different industry publications, participated actively in six major workshop type meetings or seminars with groups having a total membership of 20,000 firms, distributed 2,000,000 copies of *Federal Register* reprints of regulations and orders to approximately 65,000 firms and individuals and sponsored 14 exhibits at industry meetings which were viewed by approximately 26,000 people. In preparing this material, it seeks the help and cooperation of industry and also seeks industry's help in its distribution.

Do not be misled by the preceding comments into believing that the Division of Industry Advice is the only place in FDA you can come for and get help. We are only a "small goldfish" in a large aquarium. Every responsible individual in the FDA from the Commissioner down stands ready to serve you within the capabilities and responsibilities of his job. The operating Food and Drug Inspector in the field is probably the single most important person in our informational system—and representatives from all field and headquarters units make thousands of speeches, publish hundreds of articles and answer thousands of inquiries about your problems—they do the work.

I do not believe that our attitude or goals have changed but our mechanics, resources, and tools have. Our aim has always been, and continues to be, to enforce the Federal Food, Drug and Cosmetic Act to the extent necessary to give the American consumer the pure, unadulterated, and honestly labeled foods, drugs, therapeutic devices, and cosmetics to which he is entitled; and secondly to strive within the limits of our resources to see that industry is so well-informed about the requirements of the statutes and FDA policy that there can be no valid basis for court action except deliberate intent to violate the law. **[The End]**

Food and Drug Administration Plans and Programs

By A. D. DAVIS

Mr. Davis Is Deputy Assistant Commissioner for Planning, Food and Drug Administration.

THE TERMS "PLANNING" AND "PROGRAMMING" have taken on a special and new meaning in the Food and Drug Administration (FDA) during the past one and one-half years. The 1963 reorganization of our agency established the Office of the Assistant Commissioner for Planning. This planning function was given the responsibility of providing for future needs or solutions to problems by planning and developing new programs and policies.

In a recent speech, President Johnson stated: "Good management is now the top priority concern of my administration. That is why I asked Secretary Gardner and other department heads to take full advantage of the latest techniques in program planning and evaluation."

Here in the FDA, we are firmly convinced that *planning is the keystone of problem development.* With these thoughts in mind, we will devote our discussion to the mechanics of FDA's planning operations. We are anxious that you know and understand what we are planning, and how we are going about doing this planning.

Planning

First, we should remember that planning is not new. Every department, agency or other major government organization, including the FDA, has engaged in planning since its inception. Otherwise, we just couldn't have come as far as we have.

There is something new, however, and it has to do with *a type of planning* which all government agencies, including the FDA, are

rapidly turning to in an effort to manage the large, complex and dynamic programs necessary for the growth of the nation.

The term "multi-year" or "long-range" planning is a relatively new term in our government vocabulary. The term refers to comprehensive and integrative program planning extending *beyond* the next budget year.

This is planning as a *continuing* process by which an agency *establishes* and *revises* its program *goals, chooses* from alternative courses of action, and allocates its resources to achieve these goals in the most effective and *economical* manner possible.

In relating this to planning operations of the FDA, perhaps we should start by defining the problem:

One of the most challenging characteristics of the American industrial and economic system is the persistency of change. New products and new methods and techniques of production are continually being developed, creating opportunities for investment and economic growth, but also requiring accurate adjustments as the older ways and means are abandoned. This is the process of technological change.

All facets of our economy promise a tremendously expanded demand in the future:

—our universal desire for an improved standard of living;

—the increasingly large portion of our population represented by non-working elderly people;

—the tidal wave of youth bursting the seams of our school systems;

—the defense program, and our commitments abroad.

It has been estimated that just to maintain our present standard of living, we must increase our productivity 50 percent during the next 10 years. In other words, we must step up our annual increase in productivity from its traditional 2½ percent to 5 percent.

If this promise of economic expansion calls for a role to be played by the FDA *(and none of us can deny the existence of such a role)*, then the accompanying administrative problems need to be considered well in advance, along with the technical aspects so that proper arrangements can be made to deal with them. And, if in order to do this our agency must have the resolution and imagination to act on the basis of a carefully developed estimate of tomorrow's situation. then perhaps this is the definition of planning which we seek.

Steps for a Five-year Master Plan

Now, just how are we going about this job of agency-wide planning? The steps we follow in the planning operation are standard, time-tested approaches used in business and government with considerable success:

—We started with the preparation of an FDA Planning Concept to serve as a blueprint for all future planning activities of the agency.

—Next, we predicted as best we could the situations that will confront the organization in the next five years. This forecast took into consideration the many economic and demographic factors involved, many of which I referred to earlier.

—Next we attempted to identify the major problems that do or may require solution. We found, for example, that there are a number of internal matters that must be faced and planned for such things as the continuing need to plan for additional personnel, equipment, and facilities, and the need to maintain the high scientific stature of the agency, and give it visibility.

—Next came the development of FDA long-range goals and objectives for the next five years.

And, the product of all of these steps is an agency-wide five-year projected plan.

This five-year master plan must be kept current. Through this medium, the Commissioner will express his decisions on concepts, major objectives, priorities, primary missions, and uses of existing capabilities.

Let us recognize that we may have identified more problems than FDA can expect to handle with the resources likely to become available. Thus, it will be important to continuously examine the problems, the agency's ability to cope with them, the good likely to be accomplished by dealing with them, the cost in time and resources to deal with them, and the likelihood that society will support remedial efforts.

Seven Activities of the Agency

This five-year projection consists of seven program elements. Here we have characterized our principal program obligations to be in the areas of:

A. CONSUMER AND INDUSTRY INFORMATION—This activity involves the promotion of voluntary compliance and

cooperation between the public, the regulated industries, and the FDA through educational and informational means.

B. INTERAGENCY COORDINATION—This activity will intensify the efforts of our Office of Federal-State Relations and the entire agency to establish more effective cooperative programs with the States and larger metropolitan areas. It will attempt to encourage also a better integration of our work with related activities of other federal agencies.

C. MEDICAL AND SCIENTIFIC REVIEW AND EVALUATION—This activity involves the review and evaluation of industry proposals for the use of chemicals and other substances and for food standards. It provides for the medical review of new drug applications for safety and efficacy, review of proposals for clinical testing of investigational drugs and the conduct of an adverse reaction reporting program. Medical and scientific expertise is also provided in support of regulatory and voluntary compliance programs.

D. REGULATIONS—This activity provides interpretations of laws the Agency administers and establishes guidelines and rules to be observed by the affected industries. Examples are, issuance of interpretative regulations, policy statements, pesticide, food additive, antibiotic, insulin, and color additive regulations, and approval of new drug applications.

E. ENFORCEMENT—This is the basic regulatory activity and involves the development of regulatory programs, field inspectional and analytical activities, preparation and presentation of enforcement actions, and coordination of regulatory activities with the Office of the General Counsel.

F. RESEARCH AND METHODOLOGY—This activity involves fundamental research concerning the effects and interrelationships of substances occurring in the products that FDA regulates, as well as scientific experimentation to arrive at new and better methods of detecting and identifying harmful and/or insanitary substances.

G. GENERAL SUPPORT AND EXECUTIVE DIRECTION—It is from this activity that the agency's operational elements receive executive direction, overall coordination, and general staff support.

These seven programs or activities have been developed covering each of the five major FDA programs:

Foods
Drugs and Devices
Cosmetics
Hazardous Substances
Other Acts

A sixth category was added several months ago when the President signed legislation on:

Drug Abuse Control

An integral part of this step in the planning operation is:

The development of operating plans by the Bureaus in harmony with the overall plan and available financial resources. The plans are submitted to the Office of the Assistant Commissioner for Planning for review and approval.

Objectives of These Activities

As you will no doubt agree, any plan must be based upon goals and objectives and have proposed time schedules for accomplishing the desired end results. In developing the FDA long-range goals and objectives for the next five years we have spelled out what we want to do, and when we hope to have it done.

For example, in *Consumer and Industry Relations* we will strive to accomplish the programs described to you earlier by Mr. O'Keefe and Mr. Trawick. In brief, we want to encourage and assist industry toward improved compliance through self-regulation; and we want to reach on a regularly scheduled basis by 1970, at least 50% of the nation's homeowners, school children, senior citizens, etc., with advice on:

—how to get better goods and services;

—how to avoid quackery, frauds and cheats;

—good consumer practices in relation to label reading, purchase and handling of drugs and hazardous substances, etc.

Our *Interagency Coordination* objectives call for FDA to:

—Assist the states and major metropolitan areas achieve the personnel, facilities, and laws which will enable them to undertake their proper share of control of pure foods and drugs. FDA support will include training courses and subject to our obtaining the authority and funds, technical and financial assistance so that full state coverage will be provided in a significant number of the states by 1970.

—Establish a system in FDA for coordination within government and with the scientific community which will insure the optimum

retrieval and exchange of scientific information in all areas of food and drugs by 1970.

—Assist foreign governments, through the foreign aid program, to establish and carry forward food and drug programs. Here again we must seek additional authority and funds.

The *Medical and Scientific Review and Evaluation* objectives specify:

There will be a full in-house implementation of the Kefauver-Harris Amendments and the establishment of full facilities to keep abreast of input by 1968.

Insure that 75% of matters requiring medical and scientific review and evaluation will have a decision within 45 days; and an additional 20% within 90 days. In matters needing more than 90 days for a decision or for requests where outside assistance is desirable, the FDA decision-making capability will be accelerated by taking full advantage of advisory support from the medical and scientific community.

Establish a system for continuous review of new medical and scientific data, FDA policies and earlier decisions on consumer products. By 1970 basic policies and decisions will be reviewed at least once every five-years.

The Adverse Drug Reaction Reporting System will be expanded to bring in more reports and more definitive data from civilian and government medical installations. As part of this arrangement, a reporting system between FDA, the major drug companies, and the medical community will be fully implemented and the FDA machine input of processable adverse drug reaction information will be completed by 1968.

In the area of *Regulations* we hope to:

Recodify and simplify regulations for foods and drugs so that by 1970 the regulated industries, cooperating government officials and the nation's consumers will have a simple and concise guide on how FDA will administer its laws.

The *Enforcement* objectives are equally as extensive, and call for the agency to:

Expand the field program by increasing establishment inspections and sampling to at least twice each year for commodities that are likely to present health hazards.

There will be an import program by 1970, balanced with domestic activities, which will provide 50% inspection and 25% sampling at U. S. ports of entry; and:

—give potential health hazards primary attention;

—establish a foreign food and drug advisory program in at least two overseas regions;

—achieve better identification of import drug shipments through negotiations with the Bureau of Customs.

With regard to *Drug Abuse Control,* we hope

By 1970, to eliminate at least 80% of the major illegal traffic of dangerous (psychotoxic) drugs through the establishment of special field forces and the pursuit of special programs now under preparation.

In the important area of *Research and Methodology* here are our five-year objectives:

Expand the 1966 operating level of in-house scientific research programs, including methodology, 100% by 1970 on all aspects of regulated consumer commodities.

Establish an extra-mural research program with universities and nongovernment research institutes through research contracts and grants so that the program will be fully implemented by 1970.

Promote the professional development of in-house scientific and medical staff through programs which call for regularly rotating available personnel through academic, industrial, and governmental research complexes and medical, academic, and clinical centers. FDA staff involvement will reach a level of 10% by 1970.

Develop a scientific information and liaison program to help guide research in FDA and the research activities of universities and regulated industries into channels conducive to added consumer protection. This program will provide an estimated 100% coverage of government agencies, major industries and academic centers by 1970.

Expand FDA in-house scientific capability, keeping abreast of scientific and technological developments, so that by 1970 the agency will be able to authoritatively evaluate 95% of the new technological problems which may be generated by the regulated industries in connection with consumer commodities.

And finally, we have numerous objectives which fall under the category of *General Support and Executive Direction.* These include:

By 1970, assure that all of FDA's staff is housed in good quality facilities to assure effective and efficient performance of administrative and scientific work. The headquarters facilities should

be located in as few locations as possible to assure maximum effectiveness in communications. The facilities program should be consistent with the staffing and program projections to be developed within the five-year plan.

Improve science information and communications through full implementation of the Arthur D. Little report by 1969. Development of a system would be generally consistent with the proposed Department-wide science information system.

Expand and systematize in-house and extra-mural training programs for FDA administrative and professicnal personnel to assure that they are current in their occupational field and to assure attainment of the new skills and knowledge essential to their work and professional development. By 1967, these programs will have been implemented in the scientific occupational areas and by 1970 will be in full operation for all major categories.

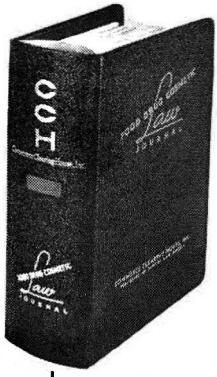
There will be a continued increase in the use of advisory groups and consultants, drawn from the medical and scientific community outside the Government. This will insure a continuous interchange of scientific opinion and provide FDA with the most authoritative position possible in the technical aspects of consumer commodities.

Summary

To sum up, this business of multi-year, agency-wide planning is not merely forecasting or predicting the future. Neither is it solely the *projection of current programs or their costs.* The importance FDA is attaching to planning is not due to confidence that the future can be predicted with any accuracy, as obviously it cannot, but to the realization that the future probabilities *must* be anticipated as accurately as possible as the only alternative to guesswork and chance. The usefulness of planning as a tool of management will depend on the efficacy with which it can deal with the future effects of present decisions. It is, to a large extent, we hope, the job of making things happen that would not otherwise occur.

It has been said that getting results in a planning program is like working with a piece of iron. If you throw it overboard into water, it will hopelessly sink. If you work on it, flatten it out, and form it like a shell, it will float. Work on it some more, hammer away at it—shape it like the hull of a ship—and before you know it that same piece of iron will actually carry weight for you. **[The End]**

Keep Your FOOD DRUG COSMETIC LAW JOURNAL on File . . .



Have a Wealth of Information at Your Fingertips

It's important to be able to find an article when you want it . . . when you need it quickly.

That's why it's a good idea to *keep your copies of the JOURNAL in a handy CCH Binder*—designed especially to hold the issues securely and in place.

There's plenty of room—each binder holds twelve numbers. Any copy may be inserted or removed easily, smoothly. It's just what every *JOURNAL* user needs for fast, convenient reference.

Made of handsome, durable black Fabrikoid—gold stamped—the Binder is sturdy, long-lasting, blends with today's office equipment, is at home on your library shelf.

There's a window label showing contents by year—to make sure you get what you reach for.

Here's your opportunity to build your own "treasure house" of usable food, drug, cosmetic law information.

Just fill in and mail the convenient Order Card attached. We'll deliver your Binder promptly and guarantee your complete satisfaction.

Price . . . $2.50 Each

CCH PRODUCTS COMPANY

A DIVISION OF

COMMERCE CLEARING HOUSE, INC.

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS OF TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN REQUESTED

SECOND CLASS POSTAGE PAID
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

A COMMERCE CLEARING HOUSE PUBLICATION