VOL. 22, NO. 12 DECEMBER 1967

Food Drug Cosmetic Law JOURNAL

Papers Presented at the Eleventh Annual Educational Conference of The Food and Drug Law Institute, Inc., and The Food and Drug Administration

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

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

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

December, 1967
Volume 22 • Number 12

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

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . December, 1967

1967 FDLI-FDA CONFERENCE

VOLUME 22 NUMBER 12

Printed in the United States of America

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

1967 FDLI-FDA Conference.—Some of the papers presented at the Eleventh Annual Joint Educational Conference of the Food and Drug Law Institute, Inc. and the Food and Drug Administration are featured in this issue of the Journal. Additional papers will appear in a later issue. The Conference was held in Washington, D. C. on November 27, 1967. The theme was "Communicating in the Public Interest."

Dr. James L. Goddard points out that there is a need for more frequent and direct communication between the Food and Drug Administration and industry. His address, "Communicating in the Public Interest," begins on page 632.

A. N. McFarlane, Chairman of the Corn Products Co., examines the idea that though industry and the government may agree on basic goals, their approaches and viewpoints may differ on how to reach it. "In the Public Interest" begins on page 638.

In the article, "Status of Major Proposals and Regulations," beginning on page 642, *William W. Goodrich,* Assistant General Counsel of the Food and Drug Division, HEW, discusses the latest developments in regulating the manufacturing of drugs.

In his article on page 647, "Is Government by Exhortation Desirable?" *H. Thomas Austern,* a Washington, D.C., attorney, examines the legal aspects of some current FDA practices.

Beginning on page 655, in his "Status and Review of the Salmonella Program," *Kenneth R. Lennington,* FDA Salmonella Project Officer, examines data reported in the past year concerning Salmonella.

In the article beginning on page 660, "FDA's Organization: The Reasons for Change," *Winton B. Rankin* discusses the major steps that the FDA is taking to meet modern day challenges. Mr. Rankin is Deputy Commissioner of the Food and Drug Administration.

Peter Barton Hutt, a Washington, D. C., lawyer associated with the firm of Covington & Burling, examines the areas where he feels the government has overextended its authority in his address, "Factory Inspection Authority—The Statutory Viewpoint," which begins on page 667.

B. F. Daubert, the Director of Nutrition at General Foods Corporation, discusses the merits and problems of the pilot self-certification program being voluntarily tested on several of his company's products. His article, which begins on page 672, is entitled "Voluntary Compliance."

The advantages and disadvantages of regulating the food and drug industry is the subject of *George M. Burditt's* article, "Good Manufacturing Practice Regulations for the Food Industry," which starts on page 677. Mr. Burditt is a partner in the law firm of Chadwell, Keck, Kayser, Ruggles and McLaren and is a member of the Illinois legislature.

John Kedzior, a member of the Bureau of Education and Voluntary Compliance of the FDA, stresses the need for cooperation between industry and the FDA in his article, "FDA's Voluntary Compliance Program" on page 682. He believes workshops and guidelines are the first steps toward better communication between the two.

Index.—An index begins on page 685 for all the articles published in the 1967 issues of the JOURNAL. The articles are indexed according to author and title, and also under appropriate general subject headings.

Vol. 22, No. 12 December, 1967

Food·Drug·Cosmetic Law
Journal

Communicating in the Public Interest

By JAMES L. GODDARD, M. D.

The Following Report Was Presented at the Food and Drug Law Institute, Inc.—Food and Drug Administration's Eleventh Annual Educational Conference at Washington, D. C., on November 27, 1967. Dr. Goddard Is the Commissioner of the Food and Drug Administration. The Succeeding Articles in This Issue Were Presented at the Same Conference.

I SPEAK FROM THE VIEWPOINT of a Government official. My remarks may apply only to Federal agencies—but more specifically they apply to the Food and Drug Administration (FDA). Communications by and between the public and the private sectors of our economy have been a major concern for me as Commissioner. Some of my impressions may or may not be a dispassionate appraisal of the art of such communications. but I assume you will take this into account.

While there are many different and even divergent points of view, there is nevertheless a common denominator for government-industry communications with the public. It is a top management responsibility; it is interwoven with policy and decision making.

So the first rule we would follow is that of management involvement. When we speak of communications in the public interest, we are speaking of the degree to which management is actually committed and ready to serve the public interest. There can be no question about this in FDA. We are fully committed to serve the public interest; it is our mission. Therefore, our communication with the public is an obligation—not an option.

My counterparts in industry—top management in the individual companies—can elect not to communicate with the public—or to communicate only when they wish to—or to communicate only when forced to—or to communicate openly at every conceivable opportunity. But we have no such options.

As head of a federal agency I am obligated both by law and the nature of my assignment to communicate freely and directly with the public. As you undoubtedly know, our legal obligation was recently re-defined under the Public Information Act, which took effect on July 4 of this year. This law has reinforced FDA's "open-door" policy, while giving us new cause to respect the confidentiality of trade secrets and certain other exempted information.

Most of you are also familiar with Section 705 of the Federal Food, Drug and Cosmetic Act. This is our authority for publication of notices of judgment. But we should also bear in mind the final sentence in that section. It reads:

Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

In addition to the legal obligations for public announcements, we feel the need for what I call "responsive management." Frankly, I do not subscribe to the concept of remaining silent until I am required to speak. The notion that silence will always provide some kind of protection for public officials is a false notion, in my opinion.

But when we speak out, we must do so in the service of the public. I want to emphasize that, because it is germane to this institute's program. We all have to distinguish between those communications for a special audience, for *a* public, and those for all citizens, for *the* public.

The FDA has frequent, direct and swift communications with its special audiences, the different individual businesses subject to regulation. These communications are usually private during the period of investigation. During this time we are acting in the general public's interest, but the rights of the company and its officials, as well as our ability to achieve the maximum during these discussions, preclude public announcements. This is the period which leads to the action ultimately to be taken in the public interest. That action is a fact to be announced or reported.

Thus, almost everything we do at the FDA eventually leads to some form of communication with the public. Therefore, our attitudes,

our judgments, our actions are necessarily influenced by how we measure the public interest.

There has been—and there always will be—a great deal of discussion about how you do this. I do not claim ultimate wisdom in this respect. I have no secrets to share about this measuring process. I do, however, occupy a position which requires me to make judgments on the basis of all the information available.

The laws Congress has enacted, the regulations we have promulgated and the decisions the courts have rendered provide us with ready guidelines on what is and what is not in the public interest. This body of legal documentation is based upon past experience. Congress enacted the laws in response to citizens' demands for protection in the marketplace. The laws were designed to rectify situations deemed to be contrary to the public interest. When situations become a matter of congressional concern, it is because Congress is the most effective instrument of progress for a citizenry whose interests are not being satisfied.

Therefore, we have a great deal of past experience to draw upon to help us measure what might be termed the public interest today. And in looking at the past we see a pattern which seems to reveal with a good deal of clarity when the public interest is not being served. The key element in this pattern is the absence of business leadership in recognizing and meeting the public interest.

The FDA does its work within a national framework of offices, agencies, organizations and institutions concerned with the people's health.

Although the FDA has a rather specific mission within this framework, we try to carry out our responsibilities for consumer protection within the total context of America's health needs. When we look at the health effort from the viewpoint of the collective national self-interest, we are forced to look at the total environment of health, much as the individual concerned citizen sees it. He looks to his Government to provide a united effort to protect him from all health hazards in his environment. Agency jurisdictions don't interest him, but the overall effort does.

Today, there is a new concern emerging. The public demands assurance as to the quality of its drugs, its medical devices and its food supply. The concern for quality is directly related to the public self-concept of being in good health and enjoying economic prosperity.

In response to this concern, we are communicating with the public, trying to satisfy its quest for assurance. And it is not easy by any means. We become deeply involved with words like "Salmonella," "subpotency," "mycotoxins," and "contraindications." We have to use these words to be accurate. Yet, as we develop and use this new language, as we attempt to define its new "techno-terminology," perhaps our communications will become more meaningful.

While we cannot and do not avoid responding to questions from the general public, our primary efforts to protect the public interest are actions and communications directed toward those who fully understand the new language. When we are effective in these communications, we are able to solve problems and reduce public uneasiness. For example, part of the question of drug quality is related to communications between the 900 firms that make prescription drugs and the 300,000 doctors who prescribe them. The problem is complicated by the fact that about 7,000 drugs are marketed as 22,000 pharmaceutical products.

A National Drug Compendium

The practicing physican must make a choice for each patient. He must do so on the basis of all the prescribing information at his disposal. Unfortunately, he has no impartial, up-to-date, complete and accurate reference where he can readily find the crisp, complete prescribing information about all the drugs available.

Today's busy practitioner needs such a reference to help him make his decisions about drug therapy. The need for better therapeutic knowledge was forcefully stated by Dr. Dale G. Friend in a *Journal of the American Medical Association* editorial. I should like to quote one salient paragraph from that editorial, which appeared in the issue of May 8, 1967:

> To any careful observer with knowledge in the field, it has been obvious for some time that the practicing physician is so poorly grounded in therapeutic knowledge as to be incapable of properly evaluating literature, claims, and advertising and unable to use properly many of the agents that are now at his disposal. His training has been so inadequate that he is often pursuaded by company representatives, journal articles, or advertisements to use a drug when he is in no position to evaluate its real merit adequately. This results in the patient's receiving inadequate benefits from therapeutic agents.

I agree with Dr. Friend; physicians should have better training in order to make rational use of today's drugs. And he should have better current information references as well. That is why I have continued the discussions we have been having with trade and pro-

fessional groups for nearly two years on the concept of an up-to-date National Drug Compendium for every physician and pharmacist.

The objective is to provide sharpened, complete prescribing information about all drugs—generic and brand name. The information should contain the latest approved labeling. It could be organized so the doctor could get a complete picture of all similar drugs.

We are still hopeful that the project will be carried out by private enterprise, possibly by the pharmaceutical industry itself. To encourage this, we are willing to remove the requirement—with some obvious exceptions—that the final printed labeling be on or within all prescription drug packages.

If the industry would take the initiative today, I believe we could see a compendium published within 18 months. But if private initiative cannot solve this communication problem, the Government will. Such a course of action is already in the public interest.

This leads me to another aspect of our definition of the term. Our basic attitude is to respond to the public interest with information that contributes to the protection of the life, health and safety of the consumer. FDA's communication functions are positive elements within our problem-oriented planning and programming. We are not set up merely to publicize the violations of the firms we regulate; we are organized to use information as one of several methods of providing consumer protection.

When a faulty product we consider a health hazard has reached the consumer, we must do all we can to communicate this fact to all consumers, to give them all the information about the hazard and recommend any action they might take to minimize or eliminate the risk.

Whether the firm will communicate the facts to the public is up to the management of that firm. It has been and remains FDA's policy to allow the company to have the option of alerting the public. If they do so promptly and accurately, FDA is satisfied. If not, then we must.

I can appreciate the difficulty of such a management decision by my executive counterparts in industry. I have had the opportunity in the past 21 months to become acquainted with many presidents and board chairmen of firms in the regulated industries. Our reasons for becoming acquainted have not always been pleasant, nor have the occasions been conducive to establishing lasting friendships. How-

ever, they have provided opportunities for each of us to observe the other in action when real issues of public interest are at stake. Early in these conversations it becomes quite apparent whether or not we are to find resolution on the basis of the general public good. The discussions have gone both ways. But they do go the way of the public interest often enough for me to say that I am not despairing of business leadership in America. Impatient—yes. Despairing—no.

In the drug industry, we are observing the evolution of a revised management awareness of public concern for product quality and availability. In the food industry, trends indicate a new management awareness of consumer preferences and concerns for top quality products. And there are signs of better, freer communications developing within the cosmetics industry, as well as between that industry and the government.

Perhaps I am overly optimistic, but I believe we are approaching a new era of government-industry relationships. We are coming together less often as adversaries and more frequently in search of common ground for the resolution of our problems. I should like to say that we do have a common ground provided for us. It is the public interest. If we meet there and solve our problems, we are not going to have any difficulty in communicating with the public. We will have a good message to send and it will be gratefully received. **[The End]**

DRUG REGISTRY SYSTEM BEING ESTABLISHED

A drug registry system utilizing numbers to identify all pharmaceutical products is being established by the Food and Drug Administration. The registry will facilitate the handling of drug information by using a computer system recently installed in the FDA's Washington laboratory building.

Non-changeable numbers will be assigned to prescription and over-the-counter drug products, and each number will represent a specific product, manufacturer, dosage form, and dosage strength. Each product will be described in terms of its generic name, trade name, and ingredients with a change in any of those items requiring the assignment of a new product number.

The FDA said that a directory listing products by name, manufacturer, dosage form, dosage strength, and identification number will be published early in 1968. Procedures for the assignment of numbers to products, the FDA noted, will be announced soon.

In the Public Interest

By A. N. McFARLANE

Mr. McFarlane Is the Chairman
of the Corn Products Company.

AS GOVERNMENT OFFICIALS, and as businessmen, we agree, I believe, on some fundamental views and goals. We are all primarily concerned with the welfare of consumers. We recognize, moreover, that consumers are people, not statistics—a multitude of individuals representing greatly varied combinations of age and ethnic groups, incomes, desires and needs. And we certainly agree on our primary mutual obligation: to serve and conserve the consumer's health and well being.

While we agree on basic goals and responsibilities, we may approach our objectives through different methods and from different viewpoints. This is understandable and even not undesirable, because each of us brings to our relationship the sum of his particular training, experience and background; his perspectives on social and economic values—his "upbringing," if you will.

Diversity of viewpoint explains, I believe, why the language of assent may occasionally sound like the language of disagreement. We may mean basically the same thing, but the form our words take sometimes makes it seem we disagree with one another.

When a government official says, "Fraud must be prevented" . . . and a businessman says, "Consumer trust must be earned" . . . we mean basically the same thing: "Fraud will not be tolerated."

When government says, "Products must be absolutely safe" . . . and business says, "Let us police ourselves" . . . we both mean basically the same thing: "Hazards to health will not be tolerated."

When government says, "The rights of the consumer must be protected in the marketplace" . . . and business says, "The consumer must have free choice in the marketplace" . . . we both

mean basically the same thing: "The mission of our marketing system is to properly serve the consumer."

Or when government says, "Labels must be more informative" . . . and business says, "We must be free to advertise and promote" . . . we mean basically the same thing: "Information is a necessary ingredient of a free market system."

Yes, we do agree basically on many of the goals we seek. Our differences, when they occur, seem to focus on the means to accomplish these ends, and more specifically on the relative merits of, and needs for, governmental regulation and self-regulation.

One of our mutual challenges is to protect the public from those few who would pursue self-defeating, improper practices, and, at the same time, not interfere with the ability of the majority of businessmen to serve the public responsibly.

Different Perspective

On this point, I'd like to suggest a little different perspective on this concept of regulation.

How strong the regulatory hand should be is a question which goes far beyond the relationship of government and business. It arises wherever authority is involved—in the parent-child relationship, in the military, and in the corporation, too. Let me give you an example. Now and then we will find a sales manager who seeks improved performance from his sales force. He believes some of his salesmen are not really on the job, or are violating this or that company rule. So he orders his salesmen to make more frequent and detailed reports to headquarters on customer calls, travel schedules, expense accounts and so forth. He tightens up the rules. But regulations geared to less responsible types drive away the responsible producers. Inferior producers require more curbs. More curbs mean more of the better men leave. As the calibre of man declines, the curbs must increase. An so on in a vicious circle, with the company the eventual loser—in spite of the original good intentions of the sales manager.

Regulatory zeal can then manifest itself in any human endeavor and, without ever intending to do so, can defeat some broader purpose —of encouraging initiative, of building responsible behavior into individual activity, of creating a desire to do better.

Moreover, as regulations are placed on more and more activities, the cost of posting a policeman at every critical point becomes prohibi-

tive. Eventually we could be met with a choice: Will we rely on the responsibility of the individual . . . call upon him to pay his debt to society—and encourage him in every possible way to exercise himself accordingly? Or will we deny individual responsibility and keep people in line only with the heavy hand of authority? To me, there can be only one choice. The amount of control sufficient to prevent wrongs from happening would be an intolerable burden not only on the regulated, but also on the regulatory force—indeed the entire structure of our free society would crumble under its weight.

This brings us back again to the basic goals and responsibilities shared by business and government. We are moving into an increasingly complex era, but essentially the aim is the same as always: to get what we produce into the right hands, in the right form and quality at the right price, at the right time. The pace is forever quickening, and to keep up involves all the skills and ingenuity of business and government—in terms of finance, research, supply, production, quality control, inspection, marketing, advertising and promotion and government regulation.

Two Problems

Obviously we do not have all our problems in hand. I would like, in fact, to suggest two large problems which face us.

One of these involves procedures of educating consumers in safe handling of food in the home. There is no question that in this country today the degree of safety of our food supply is greater than at any prior time. We expect scrupulous attention to sanitary practice in food processing plants. We have a well codified set of food laws, and highly dedicated administrators of the laws within the Food and Drug Administration (FDA). Dereliction makes news only because it is so rare.

But we have much to do in controlling food-borne illness after the homemaker makes her purchases. The National Health Survey estimated eight million persons suffered digestive ailments in 1963, second only to respiratory illness. To combat food contamination we cannot stop at the processing plant. We must continue our efforts to teach the American housewife how to maintain proper sanitary conditions in her kitchen—and we share a common interest in finding a middle ground between alerting her and frightening her.

The second problem concerns the international area; very briefly, the potential threat to free competition posed by restrictive international food laws.

As many of you know, six years ago the Food and Agriculture Organization and the World Health Organization (FAO/WHO) joined together under the auspices of the United Nations and established the FAO/WHO Codes Alimentarius Commission to write a code of food standards for international trade. The Commission has made great strides toward agreements capable of cutting through the tangle of special interest.

Surely this is not the time or the place to discuss the merits of tariffs, quotas or other devices intended to protect domestic producers in this or any other country. To the extent we have opportunity, however, we must continue our efforts to prevent food laws from becoming instruments which interfere with free consumer choice and free competition in trade anywhere, at home or abroad.

Conclusion

Let me summarize briefly my own feelings about this joint meeting here today and the opportunity it affords us.

This is an "Educational Conference." And fortunately we are far beyond the point of debating the question of which among us is most in need of education. Because the very fact of joint sponsorship of this conference by the FDA and the Food and Drug Law Institute offers its own answer: all of us stand to gain by learning from each other and by sharing information and viewpoints.

The American people will be the true beneficiaries of this process of educational give-and-take. Let me underscore this thought by quoting on the subject of education, a learned political scientist and distinguished jurist, a Scotsman who lived a century ago. "Education," said Henry Peter Brougham, "makes people easy to govern."

A sound relationship between an informal people and its government is a primary requisite to our continued progress as a nation.

[The End]

Status of Major Proposals and Regulations

By WILLIAM W. GOODRICH

William W. Goodrich Is Assistant General Counsel of the Food and Drug Division of the U. S. Department of Health, Education and Welfare.

IT IS, INDEED, A CHALLENGE TO PRESENT EVERYTHING DIFFERENT, everything new at the Food and Drug Administration (FDA). I must proceed on the assumption that all we have done, and all we have proposed, has not been wholly acceptable to the regulated industries. We are, nonetheless, pleased that a substantial consensus was achieved in placing the initial regulations under the Fair Packaging and Labeling Act into effect.

We are hopeful that our new regulations designed to improve the quality of New Drug Applications (NDA) and comparable proposals for revision of Food Additive petitions can be moved ahead with mutual benefits to those regulated and to the public.

We are striving to digest the voluminous comments we received on the proposed prescription drug advertising regulations, with the goal of creating a better basis for understanding with both advertisers and drug producers.

We stand at the threshold of implementation of the massive efficacy review which is nearing completion by National Academy of Science-National Research Council (NAS-NRC) Drug Efficacy Review Panels.

We have some new ideas for legislative improvements—new device legislation and legislation to establish a compendium of prescribing information for all of the prescription drugs available to the profession. The vitamin-mineral regulations await the appointment of a hearing examiner and the beginning of what promises to be a most protracted public hearing. The color additive regulations are under consideration by a United States District Court.

Procedures for carrying out the Freedom of Information Act have been developed and Information Centers have been placed into operation.

There are some old and new food standards proposals. We have begun to develop new regulations for good sanitation practices in food establishments, as well as to improve the existing good manufacturing practices regulations for drug manufacturing establishments.

We have set out to answer the question of therapeutic equivalency of drug products, whether sold by generic or trade names. And we have established a National Center for Drug Analysis to monitor the quality of all drugs in the market. The controversy over the use of the generic name "every time" a trade name is used in labeling and advertising has been settled. Great progress has also been made in carrying forth the administration of the Drug Abuse Control Amendments of 1965.

Finally, I should note the development by both FDA and FTC of regulatory guidelines for the labeling and promotion of OTC analgesics, as well as the FDA publication of guidelines for oral contraceptive labeling materials intended to be distributed directly to the users of these drugs.

Merely running down this list demonstrates that much more time than I have been allowed would be necessary for any really meaningful explanation of all the issues they present. But this does serve to highlight the point that FDA's days are active ones, full of implications for us all.

Five items of major concern seem most suitable for our brief dialogue today. These are:

improvements in the quality of medical and other scientific data presented to support NDA and food additive approvals;

revision of the prescription drug advertising regulations;

the administrative and legal steps that will be required to carry through on the NAS-NRC efficacy review;

the things that remain to be done to place the Fair Packaging and Labeling Act fully into operation; and

the development of regulations to assure good manufacturing practices in food establishments.

This, by no means, implies that there is nothing to be said about the forthcoming vitamin-mineral hearing, the color additive regula-

tions, the proposed compendium, or device legislation. It means only that the clock is racing, and hard choices had to be made about the issues to be covered in a short presentation.

Improvements in the Quality of Scientific Data

Everyone, and FDA is not the least of these, wants prompt and efficient processing of these applications, which must precede the commercial exploitation of new drugs and food additives.

Our analysis shows that the principal causes of delay (although not the only causes) arise from the disarrangement of these presentations and the kind of data they contain. In a ten-month period in the last fiscal year, the Bureau of Medicine issued 336 letters describing applications as incomplete and not approvable.

Our objectives in the new regulations are threefold. We want to be sure that the petitioners and applicants themselves fully understand just what data they have assembled to support the approval of new drugs and food additives, that they explain why they think their data supports the requested approvals, and that the data are arranged in a cohesive fashion that will facilitate its prompt review.

Most of our proposed solutions are elementary indeed. We want the material adequately indexed and summarized. We want the petitioner's or the applicant's explanation of the rationale of his proposed approval. We want reports of all the adverse results known to the applicant, along with his evaluation of their significance. And we want assurance that the data will not require endless requests for explanations and supplementations.

The new drug regulations have been in effect a little more than three months, so we have not yet enough experience with them to say that they have solved the problems of delay. But we have hopes that they will do so.

The major comments on the food additive proposals request a rethinking of the whole problem of indirect additives. This rethinking will be done. But the time plainly is at hand now to do something to cut down the number of these applications that are incomplete, as well as the number of incomplete NDA's. New times require self-evaluation of data before they are presented as a five-foot-shelf of statistical miscellany to be sorted out by the governmental evaluators. This is what the new drug and food additive proposals are all about.

Revision of Prescription Drug Advertising Regulations

The initial regulations applicable to this important form of communication between drug producers and drug prescribers were placed into effect in early 1963.

We started with simple requirements to allow maximum opportunities for moving with the industry and the advertising agencies to reform Rx advertising practices, but these regulations have not fully achieved the necessary improvement. Actually, within the past eleven months, we have had to request more than a dozen firms to communicate by letter to prescribers to correct faults we found in their advertisements.

The complaint most generally expressed by the firms in our discussions with them has been that the existing regulations are too vague—that the firms did not understand what it was we wanted them to do. So we have presented detailed specifications of our expectations as to what should be said and what should be avoided in prescription drug advertisements.

We are disappointed, but not dismayed, by the comments offered in opposition to the proposals. Without doubt, there is room for improvement to avoid some of the extreme interpretations placed on the proposed regulations by those who commented. It is also essential to proceed with the required steps to place new regulations into effect. We have met with representatives of the pharmaceutical industry to identify the points at which language changes can eliminate misunderstandings, as well as the points of vital interest to them and to us. The next step is to publish final regulations and to invite any objections that may possibly require a public hearing.

Implementation of the NAS-NRC Efficacy Review

This review, as most of you know, was undertaken to evaluate the data available to support promotional claims of effectiveness made for most of the prescription drugs now in clinical use. These drugs were approved for marketing on the basis of safety alone. The requirement that applications include substantial evidence to support claims of therapeutic, prophylactic, or diagnostic effectiveness was added by the Kefauver-Harris Drug Amendments of 1962. The Amendments also charged the Department with the responsibility of reviewing the efficacy claims of the pre-1962 new drugs. We were fortunate that the NAS-NRC agreed to make the initial review for us. Using panels of this Nation's best medical experts, about 3,000 drugs

have been, or soon will be, reviewed. And when the reports come back to FDA, steps must be taken to carry out the medical judgment on promotional claims, either through voluntary compliance or regulatory action.

The procedure for doing this has not been fully developed. But it can be said that any procedure must include (1) review of the reports; (2) communication of the reports and FDA's judgment about any needed product or labeling changes to the affected drug producers; (3) a mechanism for allowing the companies to make the labeling changes they accept and to contest those with which they disagree; and (4) follow-up enforcement action.

The completion of this review and the modernization of prescription drugs and the labeling approved for them during the 25 years before passage of the Kefauver-Harris Amendments is a task of the highest importance. As Dr. Goddard has said, it offers a chance that may never come again to utilize these reviews for the initiation of a national drug compendium, placing before prescribers accurate and adequate prescribing information about all the drugs available in the marketplace, as well as the sources of drug supply.

Fair Packaging and Labeling Act

We have studied the comments presented by drug and cosmetic packagers and will soon be able to act on the proposed regulations applicable to those consumer commodities.

Improvement in labeling and packaging for foods, indeed for some drugs and cosmetics as well, is already evident. We have not yet drafted the discretionary regulations, regulations applicable to cents-off and other bargain promotions, to "large", "medium", "family", and "king-size" containers, to slack-filling of packages, to improved ingredient information, and to exemptions for some products. We will begin this task in early 1968.

Manufacturing Regulations for Food Products

Unlike the drug provisions of the law, the food sections do not specifically authorize this kind of regulation. However, the Court of Appeals for the Seventh Circuit said several years ago that if the Department wanted to improve the sanitary practices in food establishments, it would be likely to receive the support of the Courts if it first adopted definitive regulations describing the expected improvements. Regulations on this subject have been drafted and should be announced shortly. **[The End]**

Is Government by Exhortation Desirable?

By H. THOMAS AUSTERN

Mr. Austern Is a Member of the Washington, D. C. Law Firm of Covington and Burlington.

SOME MONTHS AGO A STARTLING SOLICITATION came across my desk. It offered a sampling of what it called the FDA "Hot Line." One could, for a price, telephone and, on any key FDA question, have read to him a taped transcript of a current interview with the key FDA official dealing with it.

To one familiar with food and drug regulation for more than 35 years, and who had been privileged to know every Commissioner who ever graced that office, that solicitation was indeed provocative. It started me thinking about the contrast between how the law was administered and enforced three decades ago, when the basic 1938 Act was passed, and the FDA world of today with its official speeches, almost daily press releases, a two-colored FDA Paper, Pink, Blue, Gray and Gold Sheets, newsletters, multiple Congressional investigations and hearings, and the Annual Educational Conferences.

The poet of course lied when he said that age has its victories. Yet even if decades of experience do not guarantee wisdom, and the day a man resists new ideas he has become mentally obsolete, the years do afford a perspective that permits one to ask questions.

Prejudices of a Lawyer

I must, however, first briefly expose my biases. I am a lawyer. Many in this audience would loudly applaud what Dick, the butcher, urges in Henry VI: "The first thing we do, let's *kill* all the lawyers."

Despite the calumny heaped upon them from the days of Justinian to those of Goodrich, lawyers never can escape their training. They have a developed passion for documented facts, as distinguished from subjective opinions and buried predilections, however well motivated. They believe, as an article of political faith, that good democratic government requires that statutory procedures ordained by Congress, should be meticulously respected. They harbor the conviction that no man, no product, and no industry should be condemned without a fair trial.

In this country, lawyers have also won recognition for the proposition that in many circumstances provocative publicity can, and often does, prejudice the necessary dispassionate and objective inquiry into culpability or innocence.

Another legal bias that must be exposed is the persistent and reiterated belief that the sanction of absolute criminal liability is not desirable in this field. Of course, Justice Frankfurter once did observe that American law affords greater constitutional protections for what feeds the mind, than for what feeds the belly.

Criminal penalties applicable, without inquiry into knowledge or intent, might be socially necessary to deter statutory rape, or to punish a barkeeper who illegally sells intoxicating liquor to a mature-looking bearded juvenile proffering a false I.D. card. But to apply absolute criminal liability for violation of any part of the current complex, cross-numbered, and confounding compendium of present day Federal Register FDA regulatory output is impossible to accept. Perhaps for that reason FDA penal punishment is only rarely sought even though the right to do so is defended to the death before Congress.

Most lawyers remain unconvinced that we need a rule that makes every company official criminally responsible, without either knowledge or intent, for any misreading by any other company employee of the pellucidly plain, semantically subtle, and always crystal-clear wording of every FDA regulation.

Others dislike, both emotionally and philosophically, every type of *preclearance* of human activity, the current drift to saying, "Don't act until an omniscient government gives you specific permission."

A man must always be legally responsible for what he does, but only in rare instances should he be required to get official preclearance for his action, whether you call that licensing, an application for approval, or a stop-order.

In the field of public health, that is a hard battle to fight. But those who do *not* want their children to live in a completely Orwellian society must meet that challenge wherever it arises.

For driving licenses, new drugs, pesticides, and food and color additives, one must now yield to the created complexities and problems of modern day life. But in economic areas, there are still many who will rally against any type of required preclearance or obeisance to comprehensive governmental prior blessing. The polemics employed derive from a basic American attitude about freedom and individual initiative and responsibility.

Among my many other biases is an ambivalent attitude about administrators, many of whom I have admired as men and enjoyed as friends. The fact that a man has served the government for his entire adult life does not warrant invidiously calling him a bureaucrat, or remotely denigrating his knowledge or motives. By the same token, years of service do not confer sagacity, or automatically provide that up-to-date knowledge that should be the keystone of expected expertise.

Public Interest and Consumer Education

Let us return, however, to publicity, pamphlets, speech-making, dope sheets, and the public interest in consumer education.

It is an accepted axiom of law enforcement that the prosecutor always has discretion. If that were not true, the Federal courts might be jammed with Mann Act prosecutions. Even though there must inescapably be large discretion residing in the prosecutor, no responsible lawyer can offer that as a basis for counselling a violation of law. That a violator may get away with it because of lack of enforcement funds or priorities does not make him any less a violator. Still, it is a fact that everyone would like to know where he stands, particularly in the face of an inescapably complicated regulation.

Each of us must also recognize that in the vital and complex area of FDA enforcement, subjective evaluations as to what should get enforcement priority cannot be escaped. Budgets are not unlimited, however vastly they are increased.

Every fair-minded man also recognizes that voluntary compliance presupposes that there be knowledge, explication, and, hopefully, understanding of what each new regulation requires.

Equally important, no one has ever challenged, and in Section 705 Congress specifically provides for, the FDA taking to the air and the public press to protect the public when there is imminent danger to health, or of gross deception to the consumer. Section 705, however, granted only limited authority, as shown by the further provision that it should not be construed to preclude the collection and reporting of FDA research investigations. Commissioner Campbell agreed at the 1933 Senate hearings that authorized publicity "would not be new, and would not be gratuitous on the part of the Department."

Sometimes I suspect that both those who drafted Section 705 and its Congressional sponsors of 1938, would be surprised, and perhaps shocked, at the weekly mimeographed mass of materials that today has become routine, and seemingly required reading.

Reaching Objectives

Granting that there must be priorities in enforcement, that dramatic publicity may sometimes be required to protect the public health or to expose major fraud, and that desired voluntary compliance requires education and understanding by those who are regulated, the real question is whether the way those objectives are today being sought is the best way.

Lately, many have expressed restiveness on that question. It therefore may be useful, and undoubtedly will be provocative, to report a few of the chief areas about which concern has arisen.

The first derives from the basic rule that where an administrative official is charged by statute with the responsibility for deciding issues of law or fact on a *record,* even the most guarded *prior statement* of his position will disqualify him from acting. That is both a rule of fairness, and in many situations also a judicial requirement.

On French flag vessels, there used to be two captains, one to run the ship, and the other to socialize and talk with the passengers. Perhaps the end product of the current trend of agency publicity may be two agency heads, one to talk about its interests and objectives and conclusions in public speeches, and another to keep an open mind for the evaluation of the record.

Many businessmen also have difficulty in penetrating what is called the institutional agency decision. There are, of course, legal limits in the Administrative Procedure Act.

There is also the desirability that governmental action not only be fair, but that, like Caesar's wife, it always appear to be wholly chaste. Where the same administrative officer conducts the investigation, writes the regulation, appears as the principal opinion witness at the hearing, and then evaluates his own testimony in preparing findings and a final order, both requirements suffer an inescapable credibility gap.

Second, the line between what the statutory provision or regulation really requires and what the FDA would like to have it mean, but might never attempt to enforce, often becomes blurred. I cannot remember whether it was William Goodrich or another lawyer who long ago invented the phrase "jawbone enforcement." I have always thought it meant that an agency could advance its regulatory scope in test cases, and frequently did so in answering inquiries.

To expand a regulation in response to an inquiry very often will result in unfairness. Some will acquiesce. Others will adhere to the text, and await a judicial test in an enforcement proceeding. But I have never understood why any agency should issue a Statement of Policy, as a part of "jawbone enforcement," when in reality it would not promptly back up its policy statement with rigorous enforcement. Doing that is not education, but only exhortation. And when a Statement of Policy is accompanied by an exuberant press release, its justification has puzzled many.

Third, some caustic critics urge that there is a difference between consumer education and some types of Madison Avenue publicity. No one quarrels with FDA efforts on consumer education. But exposition ought to avoid even inadvertent condemnation. Disagreement as to objectives or need ought not to call into question anyone's motivation, however lively a news story it may generate.

What "jawbone enforcement" often leads to are exaggerated and distorted press reports. Sometimes those suggest widespread violation where in reality none exists. To proclaim in official documents that those who insist that the Section 704 factory inspection language means only what it says are to be equated with those "suspected of violation" may afford a legislative stance, which can soon be demolished, but is not conducive to accurate press reporting.

The suggestion, once officially advanced, that newspapers and other media ought to establish an FDA "press beat" will, some believe, soon sadly boomerang on everyone. Some press writers often will beat down as hard on the FDA as on the regulated in-

dustries. Many doubt that lurid press reports, or dramatic TV sequences, promote responsible compliance.

Fourth, there is a growing feeling in some quarters that the economic impact of an FDA press release often exceeds as a real penalty what an unintended violation should warrant. Recent episodes need not be rehearsed. Many, however, will remember the 1958 Cranberry Episode where an unfounded and exaggerated press conference by the Secretary ruined an entire industry overnight. At least, Congress indicated it thought that was the case when it voted for monetary reparation.

I do not charge that the FDA always mentions brand names when it publicizes voluntary recalls. But the press inevitably does so. No one would disagree with Mr. Cron when he recently observed that the FDA ought to deploy its "press machinery to protect the consumer from an offending product, not to punish an errant company." Where the line is hard to draw, it may be preferable not to ink the pen. As Marshall McLuhan has suggested, too often the medium is the message.

Public Image of the FDA

The law specifically authorizes the publication of Notices of Judgment. Yet, in those new and fascinating FDA papers, denoted "The official magazine of the Food and Drug Administration," there are illuminating quotations and discussions and colorful illustrations, but the hard core Notices of Judgment are no longer as complete, even at $5.50 a year. Perhaps there the magazine summary does not fully recapitulate the full package insert.

Next, I have often thought that there must be some relation between what goes on in Congress and the new press image of the FDA. No one will deny either the right or the public importance of Congressional inquiry into any agency action, or in as important a regulatory field as FDA. Legislative forecasting is a legitimate game, which in Washingon has more avid players than might be found at any racetrack, often with the same success. But there are dangers in unrestrained Congressional zeal in investigating.

As I pointed out some years ago, it would take a courageous administrative official to approve an IND or a new drug knowing that he faced the hazard of later being made to appear to have been medically uninformed, unwise, or even subjected to undue

influence, when years later he is interrogated before an aggressive Congressional committee whose interest in publicity is never minimal. I believe that Congressional inquiries involving the conduct of FDA medical officers, or the propriety of their conclusions, ought always to be held *in camera* and not on a public pillory.

Publicity also breeds counter-publicity. Each in turn yields controversy, agitation, often consumer apprehension, and, inescapably, more Congressional interest. How much the boiling of that publicity pot contributes to efficient and effective regulation is often open to question.

Neither in industry nor in Government do Americans want to muzzle anyone, but censorship is not to be equated with self-restraint in provocative public talk or even condemnation.

Lastly, I subscribe completely to the view that the job of protecting the public interest should be a cooperative endeavor. The regulated industries have the obligation to keep the FDA fully informed and up-to-date. But I see no reason why what is discussed at every conference, or in every informal exchange of data or views, requires publicity or press releases. The new Public Information Act does not require that, and misrepresentation to any agency *is* a Federal crime.

The ancient legal rule that at a trial there can be no discussion of what was previously said in settlement efforts, has a lot of common sense behind it. Many scientific and economic questions are not as black and white or as simple as some reporters would want.

This is not, I suppose, the forum for debate about some abiding legal questions.

The aphorism that in the privacy of his own showerbath every businessman thinks he would make a splendid lawyer obviously now extends to medical doctors, statisticians, chemists, food technologists, sanitary engineers, and, of course, all administrators. I shall leave that one by inviting all of those uncertified lawyers, in their new role of legal analysts, to ponder a few questions.

Why has the FDA always said that an interpretative regulation could not be initially challenged because it could later be tested when it was applied in a particular case, yet now, after the Supreme Court ruled that it could be initially challenged in certain

cases, the FDA turns the rule around to insist that every interpretation firmly has the "force of law"?

Another intriguing legal inquiry is how, when the statute commands that a determination be made on the basis of facts presented at a hearing to support it, the FDA can take the position that no hearing really is necessary because nothing would, or could be, said at the hearing that could make any difference.

Of course, I shall never understand how the separate FDA Act and the Fair Packaging Act provisions can legally be scrambled in one regulatory omelet. At the least, that confirms in part the charge that the two statutes unnecessarily overlap. More important, it may lead to a wholesome delineation in litigation between economic issues and real questions of public health.

Conclusion

Admittedly, all of those insistent questions about publicity raise nice problems of degree. Yet, fundamentally, my hope is to see less beating of the tom-tom of publicity, because it does not mean better enforcement. The story of the boy who incessantly cried "Wolf" is still apposite. Those who remember that the publicity and screaming of the N.R.A. Blue Eagle was both short-lived and ineffective, may agree that government by exhortation can end in fatigued failure.

Recently, Professor Hazard of Chicago, in a penetrating article, summarized in learned fashion what I have been groping for here this morning. He said:

> If one could imagine a society in which administrative perfection had been so far achieved that for practical purposes all who were officially accused could be safely regarded as guilty, it is difficult to imagine how such a society could be free in any sense of the word. That would be so unless it were also assumed that a society approximating such administrative perfection were also content to limit its instrusions into private affairs to rigorously confined areas of concern, so that the apparatus of administration touched individuals only infrequently. That assumption seems wildly improbable . . . if only because technical efficiency . . . tends to inflate substantive regulation by a slow but relentless Parkinsonian process. In any event, the modern trend seems to be toward constant filling of the gap between conduct which is within the reach of regulatory technique and that which is actually regulated. This is as notable in the criminal law as it is in civil relationships.

Professor Hazard was, I remind you, talking about effective governmental control, not publicity about it. **[The End]**

Status and Review of the Salmonella Program

By KENNETH R. LENNINGTON

Mr. Lennington Is the FDA's Salmonella Project Officer.

SINCE DECEMBER 1, 1966 there have been 85 recalls of Salmonella-contaminated foods and drugs from the market. These recalls have involved a wide variety of items including chocolate, coconut products, dried yeast, animal glandular materials and finished dosage forms, frozen pies, eggs, dried milk, dog candy, enzymes, and dried mixes.

The National Communicable Disease Center Annual Summary for 1966 indicates that the infectional and mortality rate is about the same as for the two previous years, with over 20,000 human isolations reported. Sixty-nine deaths associated with Salmonella infections were reported last year. But, as recognized by public health authorities, these data represent only a fraction of the actual number of cases and the true mortality rate would be higher if there were no deficiencies in reporting.

In general, foods of animal origin, poultry, eggs and egg products, milk and meat products continue to be the most common vectors. One of the major outbreaks of the past year implicated a frozen dessert made from unpasteurized egg yolks. The product was prepared by a processor who supplied caterers for banquets. The egg yolks were from a local source, not pasteurized in accordance with the Standards. Fourteen outbreaks involved an estimated 1800 persons. The same serotypes were isolated from stools of patients as from the frozen dessert. All of the ingredients used in the dessert were negative for Salmonellae except the frozen egg yolks, from which two of the three serotypes involved in the illnesses were isolated. Based upon the total number of servings of the dessert produced by the manufacturer, and

the attack rate of the known outbreaks, it is extrapolated that between 9,000 and 21,000 persons were made ill by the dessert. We see in this episode how the product of a single plant may cause wholesale outbreaks affecting a large number of consumers over a wide geographic area.

Last year, the contamination of thyroid, pancreatin, and other drug substances of animal origin was a newly identified threat to public health. The Food and Drug Administration (FDA) formulated a regulatory and compliance program to keep these Salmonella-contaminated drugs out of drug and special dietary channels on the premise that viable Salmonellae in internal preparations are a hazard to health. It is of interest and significance that almost simultaneous with our investigations in this area, Swedish authorities noted an increasing number of infections with Salmonella *muenchen* reported from different parts of that country. Since this serotype had been comparatively rare in previous years, especially during the winter, an epidemiological investigation was carried out. Briefly, the Swedish investigations disclosed that thyroid tablets were the carrier of the infection. In all, 202 cases of direct infection were uncovered. The sale of the drug was immediately stopped and a warning against use of the tablets was released through the press and television. While we have no documented cases of infection from thyroid tablets in this country, the Swedish experience substantiates the conclusion of our medical advisors of the potential health hazard. Attention to imported lots of thyroid, pancreatin, liver powder, and similar products continues, and detentions of contaminated lots are not infrequent. Domestic producers have instituted close microbiological controls and have reviewed their processes, upgraded sanitation, and increased thermal treatment where possible. Consistent production of non-contaminated products is a goal that our industry is striving hard to attain.

Experience in the past year points to chocolate candy as a possible new problem area. At least three major producers have encountered Salmonellae contamination in finished products. The vector or vectors of contamination are as yet uncertain. The low moisture content of the ingredients, in the processing and in the finished product would not seem sufficient to support proliferation, yet we find finished candy containing a level of contamination that cannot be explained by present day knowledge. Here again industry has shown concern and a determination to ferret out and remedy the contaminating factors. At least two research projects and pilot plant studies have been arranged by industry with food science departments of state universities.

The most important reservoirs of Salmonellae and sources of human salmonellosis have been identified as livestock and poultry. It has been repeatedly demonstrated that animal feeds, especially those of animal by-product origin, frequently contain Salmonella. The United States Department of Agriculture (USDA)-Agriculture Research Service (ARS)-Animal Health Division (AHD) recently completed an extensive study which indicated a high incidence of contamination in these basic protein feeds. While the feeding of contaminated material to animals and poultry constitutes but one step in the chain of infection, it is apparent that we cannot feed Salmonellae containing feeds and have non-contaminated livestock and poultry.

The FDA has in the past year, as one of the first steps in a program aimed toward reducing incidence of Salmonellae in animal feeds, issued a Statement of Policy announcing that Salmonella in basic protein feeds of animal origin constitutes adulteration within the meaning of the Act. Concurrent with this formal position, and even prior to issuance, we held discussions with industry. FDA and USDA-AHD participated in nine workshops or Salmonella seminars sponsored by the National Renderers Association across the country. Major improvements in facilities, processing systems, sanitation, and microbiological control have already been made by the industry.

The cooperative State/Federal Program for Salmonella control in animal feeds and feed ingredients by USDA-AHD is being intensified this year. It provides for approximately 2500 rendering plant inspections with testing of finished products. At least one epidemiological study will be made of each plant showing a Salmonella positive sample. The FDA program is being coordinated with AHD and participating State officials to preclude duplication of effort.

Imported tankage, meat scrap meal, fish meal and related products are being sampled and examined. Those lots found contaminated with Salmonellae are refused entry unless they are sufficiently heat treated to destroy the organism.

The FDA and other departments and agencies of government are sponsoring important research and study of the Salmonella problem. The National Academy of Sciences, under joint sponsorship of the USDA, ARS and the Consumer and Marketing Service, and of the FDA, is undertaking a broad study of Salmonella and its impact on human health, food technology and animal agriculture in the U. S.

This study will require at least 18 months for completion and will be under the guidance of the Food Microbiology Subcommittee of the Academy's National Research Council Food Protection Committee and Animal Health Committee of the Agricultural Committee.

Among other things, the Committee will seek answers to:

What changes are occurring in the incidence of salmonellosis and what factors underlie the changes?

At what point in the chain of transmission of Salmonella infection can control methods be most effective?

How can the combined resources of government, the academic world and industry be utilized most effectively to reduce the potential Salmonella threat to public health and animal health?

FDA is also sponsoring a fifteen-month study of the scope and depth of the Salmonella problem by an independent research institute. That study will analyze the problem in relation to the total environment, the food and drug industries and man. Sources, carriers and transfer of Salmonellae will be included, and an effort made to predict the most probable sources of contamination within a processing plant and the manner in which it may be spread in these plants.

FDA is sponsoring a study at the University of Minnesota on the vectors pertinent to contamination of spray-dried milk with Salmonellae. These studies will include microbial populations of air supply, survival of the organisms during the processes, recovery of Salmonellae and levels of populations recovered by the present detection systems. Information developed from this study will be helpful and have application to the whole area of spray-dried foods, where, on basis of limited experience, we find Salmonella contamination is a problem.

The Public Health Service, the Department of Interior, several Divisions of USDA, and other government agencies also have studies underway. We are optimistic that many of our present gaps in knowledge will be filled in the near future by today's research, thus contributing to more effective control of Salmonellosis.

Voluntary Compliance Approach

Industry has been encouraged to meet the Salmonella challenge through a voluntary compliance approach, and has responded to a material degree. FDA has welcomed the opportunity to contribute

to workshops, seminars and similar educational approaches. State agencies, various federal departments and agencies, and universities have likewise participated and contributed in these activities. The numerous regional National Food and Drug Manufacturers (NFDM) Workshops, Smoked Fish Seminar, Salmonella in drugs of animal origin, the recent Workshops for Convenience Food Manufacturers are examples of this co-operative effort that we believe is more likely to achieve success than a purely punitive enforcement policy. But when voluntary compliance fails, the civil and criminal provisions of the law are available and ready.

Our basic enforcement and regulatory policy has been to notify the manufacturer or distributor when Salmonella contamination is found in a finished food product. Simultaneously, we evaluate the public health significance of the situation and when a potential threat to the public health is determined, the processor or distributor is so informed. It should be noted that when a question arises in an assessment of the potential health hazard, it must be resolved in the interest of the public. The voluntary recall has been shown to be the most expeditious procedure for removal of distributed stocks of contaminated or suspect foods or drugs from the market.

While there are many unanswered questions on the routes and mechanics of Salmonella contamination, one of the most important control measures to prevent contamination and infection is a high standard of sanitation. The basic principles of food hygiene must be observed if we are to have a safe clean food supply. As a step in this direction, we have worked with the food industry, particularly the Grocery Manufacturers Association and developed a series of slides, directed at the food plant employee and supervisory levels, setting forth the basic principles of good hygiene and sanitation. Much more remains to be done in this area.

The microbiological hazards in our foods and, to a lesser extent, in our drugs have been exemplified over the recent past by the Salmonellae. Salmonella has been the identifiable culprit, tried and found guilty by a preponderence of epidemiologic evidence. We must not lose sight of the fact that Salmonellae are but one of a number of pathogenic organisms occurring in the alimentary tract, and that the tighter controls over sanitation, improvements in maintenance, increases in thermal processes and other actions to prevent and control Salmonellae, have direct application and protective effect against infection of our foods by viruses and other bacteria of intestinal origin. **[The End]**

FDA's Organization: The Reasons for Change

By WINTON B. RANKIN

Mr. Rankin Is Deputy Commissioner of the Food and Drug Administration.

I HAVE BEEN ASKED to report on the status of the Food and Drug Administration (FDA) organization. I can do that quite concisely. It is fluid. At any point in time, one or another of FDA's units is probably reorganizing or thinking about it very seriously. All of us are becoming increasingly accustomed to change in organization, so it is particularly appropriate to spend a few minutes looking at the reasons for such change.

We do not reorganize just to have something to do. People are disturbed by a new organization. Procedures must be changed to make the new structure work effectively. And sometimes, after the best planning we can bring to bear on the matter, we look back and find that some very important job is being handled less effectively under the new set-up. So why not just stick with the existing organization that has proved itself over a period of time?

If the goals of an agency, the methods by which it expects to achieve them, and the abilities of its people remained constant, and if the environment in which the agency exists were relatively static, then we might be able to utilize basically the same structure over a period of many years. But life isn't that simple. Our social environment is undergoing revolutionary change, and science is developing new products which in turn bring new pressures to bear upon us. People change, and their replacements do not bring the same mix of skills and knowledges as the individuals who are leaving. An agency that is to remain fully responsive to the demands being placed upon it must continually assess the demands and determine the best

way to meet them. Where necessary, the organizational structure is altered to permit effective performance. That is why we reorganize.

Modern Challenges

Certainly the demands being placed upon the Food and Drug Administration today are vastly different from those of a decade ago, and the change is even more marked if we go back only 30 years. You are well aware of the many responsibilities that have come our way in the last 30 years. Just think of the requirements placed upon the agency by such legislation as:

1. the several drug certification amendments;
2. pesticide chemical and food additive amendments;
3. hazardous household substances laws;
4. the Kefauver-Harris Drug Amendments of 1962;
5. the Drug Abuse Control Amendments;
6. the Fair Packaging and Labeling Act.

This is not all. Modern technology is producing conveniences undreamed of a generation ago. But in the process, it is generating new or increased insults to the human body. We get foreign materials, sometimes toxic, in the air we breathe, the water we drink, the food we eat. We are being subjected to noises in the cities which disrupt an orderly pattern of life. And in many other ways modern man is being subjected to stresses not previously a part of his environment. Just the business of commuting between home and office during the rush hour is enough to upset many people. Your body is not going to make a fine distinction based on the route by which it receives a poisonous pesticide. Whether the chemical arrives by air, water, or food, it constitutes an insult that must be dealt with. The various agencies that deal with pesticides, their use, and the control of excessive exposure to them must coordinate their activities to be fully effective.

As an agency primarily concerned with consumer protection, we must not only discharge well the specific duties required by the statutes we administer, but also participate actively with other consumer protection agencies and groups so that our combined efforts will yield maximum results. Likewise, our work must be carefully coordinated with the other consumer protection activities of other agencies: fed-

eral, state, and local governments; volunteer groups; in fact, all elements of society.

Now let's look for a moment at the things we wish to accomplish by change.

We must have an organization that:

1. gathers and effectively handles large masses of technical and complex information;

2. decides what present or potential problems these facts present, and determines the relative importance of the problems;

3. seeks agreement within and without the agency as to desirable methods of dealing with the problems of greatest priority and establishes a reasonable program for accomplishing the job, including a timetable for accomplishment;

4. measures the effectiveness of the performance;

5. creates a climate in which our people can grow.

And we must not only accomplish all of these activities in ways that conserve scarce skills and funds, but we must also secure cooperation from many people outside the agency, including the regulated industry.

Major Steps

Let us look at some of the major steps FDA is taking to meet the five challenges just mentioned:

1. *Gathering Information.*

For many years we have received masses of information from many sources, including applications and petitions, inspection and analytical reports, scientific literature, reports of adverse drug experiences, and research in our own laboratories. A major need is to organize the information so that it can be retrieved and used. We have established a Science Information Facility that will do this. Even before the Facility got underway, progress was made in some offices. Then, too, there are kinds of information that we do not receive now or that is received in too small a quantity to meet our needs. We will arrange to get better data.

2. *Evaluating the Information.*

When all the available facts are organized and condensed, they will show numerous areas where FDA could operate. We will not be

able to cover all of them. The question is not what we could do with unlimited resources, but what we should do with available resources.

We have established a mechanism for drawing upon outside help in our studies. We have a National Advisory Council, several scientific advisory committees, consulting groups representing other agencies and other levels of government, our own consumer consultant program, etc. Presently, the National Academy of Sciences-National Research Council, through its Drug Research Board, is helping us study the effectiveness of some thousands of drugs approved for marketing before 1962. The advice received from these sources, together with the informed judgment of experienced personnel within the agency, permit us to determine which kinds of work are most important and to assign relative degrees of importance to them. The new planning office under an assistant commissioner is primarily responsible for the evaluating activity, but many other offices help.

3. *Establishing Viable Programs.*

Having identified the problems and assigned priorities, it is necessary to establish programs to deal with them. Most consumer protection programs can be handled in several different ways. For example, one might be handled through: federal court actions; a federal educational program; state and local actions, either court or educational; voluntary industry control; or a combination of some of these.

We are anxious to coordinate our activities with and to utilize the assistance of other groups fully, and the organization is being set up to make this readily possible. We are increasingly cooperating with other agencies in many areas. Examples are cooperative programs currently underway on pesticides, the ecological effects of antibiotics and salmonella control.

We are developing closer liaison with State and local consumer protection agencies, and will, wherever feasible, hold joint planning conferences with them. Thus, each of us will know in general what the other is doing, and our work can be complementary rather than duplicative.

The regulated industries and their associations are helping to develop and present workable methods of industry self-improvement. One manufacturer is currently engaged with us in a pilot study of an industry self-certification program that offers much promise. And we are trying to achieve further protection through greater consumer understanding of and participation in our activities.

One of the significant changes that has taken place in the last two years is a shift from a commodity-oriented to a problem-oriented approach. Formerly, our field operations were directed largely toward the detection of violations of the law. This effort was related to the commodities or classes of commodities under our jurisdiction. Try as we might to arrive at a better measure, our achievements generally were measured in terms of the numbers of inspections made, the number of samples analyzed, and numbers of legal actions started. The problem was that these measures could not readily be translated into a measure of the resulting consumer protection.

What was needed was a better method of targeting our efforts, of allocating our resources according to priorities established with more recognition of the total consumer protection they would yield. In addition, we wanted a better indication of the effectiveness of performance than the yield of violations, which really is a failure-rate, not a success-rate. We believe the problem-oriented concept provides this better method of planning. We are still trying to develop the improved measure of effectiveness.

The Salmonella program aptly illustrates the problem-oriented approach. Contamination by this organism presents the same kind of health hazard whether the contamination occurs in a thyroid preparation, dry milk, eggs, candy, or a color additive. Our corrective efforts are directed at the elimination of the source of contamination from all foods and drugs. We are dealing with one health hazard, no matter how many different commodities may be involved.

All FDA offices are involved in establishing viable programs, especially The Office of the Assistant Commissioner for Education and Information, the regional assistant commissioners, The Office of Legislative and Governmental Services, the compliance bureaus, and the districts.

Some people have asked whether FDA's current emphasis on interagency cooperation and industry self-improvement foreshadows a decrease in the enforcement effort. The answer is NO. There has been no relaxation of the enforcement effort, and there will be none. We do want to help the industry understand and comply with the requirements of the law. I would hope that as industry improves, there will be less need for the various corrective actions we must initiate as a result of errors, but this change probably will be very gradual. If you will review the various corrective actions taken last year as

a result of our work (court cases, recalls, voluntary destructions of unfit merchandise, plant improvements, "Dear Doctor" letters on drug labeling and advertising errors), and will consider the volume of the products affected by these measures, I believe you will come to the same conclusion I do, that effective FDA enforcement activity has increased.

Now if you will add to these results the improvement in our handling of new drug applications and other drug matters and our problem-oriented attention to significant health problems, such as bacteriological contamination of foods, in the food area, I believe you will agree with my conclusion that the FDA record of truly significant consumer protection in the past 12 months is greater than at any other time in many years. Still, we are not content, and we expect continuing progress.

4. *Appraisal.*

The new organization will conduct studies to determine the impact of the programs on the consumer. This will require a continuing surveillance operation. We will then need a management information system to bring current appraisals to the attention of the Commissioner along with recommendations for change to increase our effectiveness. The new organization will provide for such appraisal and follow-up actions, but they are still in the formative stage.

5. *Employee Development.*

Our performance is a direct reflection of the abilities of our employees. If the new organization is staffed with people who operate in the same old way, we cannot expect to discharge effectively larger, more complex responsibilities.

We have very able, well-trained employees. So have most of the other agencies we work with. These people must have a climate in which they can continue to develop, in which they can contribute to the key decisions being made by the agency.

We have various training programs under way. Some are extensions of programs previously in effect, while others, such as the Career and the Executive Development Programs, are new. All are designed to help each employee reach his full potential.

We are prepared to help the states and cities in their training programs, and you know already of our joint efforts with industry.

Many of the decisions formerly made in Washington can be made just as well by the directors of our various offices or their key personnel. What is required is a complete understanding throughout the agency of the Commissioner's policies, of the goals, and of the guidelines that will be utilized in reaching them. We are currently preparing appropriate guidelines to help the district and bureau offices make decisions wherever practicable. This decentralization will become more significant as it continues.

Conclusion

That's a bird's eye view of the reasoning back of our organizational effort. We want to deal with major problems first. We want to deal with them effectively. We seek increased cooperation with all who can help in the job of consumer protection, including the regulated industry. We expect to give primary attention to basic problems rather than to individual commodities. We want our employees to grow, and we want to decentralize decision-making authority.

No one thinks that we have finally arrived at the organization that is perfect. But we have one that is more responsive to today's problems than it would have been without change. And it will improve.

[The End]

PRESIDENT SIGNS STATE MEAT INSPECTION BILL

The Wholesome Meat Act, applicable to meat processed and sold wholly within a state, was approved December 15, 1967. Each State is given two years to develop a meat inspection system with standards at least as strict as the federal system which applies to interstate business; however, the Secretary of Agriculture may extend the period for an additional year. The Secretary may require intrastate meat plants to meet higher standards before the deadline for state compliance if such plants are found to be selling unwholesome meat. Federal financial aid up to 50% of the cost of establishing a meat inspection system is also provided.

Imported meats are subjected to the same requirements, and horsemeat is brought within the terms of the law. Previously-applicable provisions of the Imported Meat Act and the Horsemeat Act are repealed. H. R. 12144, CCH Food Drug Cosmetic Law Reports, ¶ 1315.

Factory Inspection Authority— The Statutory Viewpoint

By PETER BARTON HUTT

Mr. Hutt Is an Attorney Associated with the Washington, D.C. Law Firm of Covington & Burling.

IT IS DISCOURAGING that virtually every discussion of food factory inspection authority is thought to require two separate and inconsistent presentations: one from an industry viewpoint, and one from a government viewpoint. This assumed dichotomy itself discloses the basic problem. There is, today, little or no agreement between government and industry on their respective statutory rights and duties. As a result, each misunderstands and mistrusts the other's motives and capabilities. The possibility of anything more cordial than an armed truce is virtually foreclosed under these circumstances.

I cannot presume to speak for an entire industry and, in any event, I would like to attempt to avoid perpetuating the antagonism inherent in setting out just one viewpoint. I therefore propose to discuss factory inspection from a more neutral standpoint — the statutory obligations themselves. I see these obligations as a set of rights and duties imposed upon both the regulator and the regulated for the best interests of the public.

Congress had two alternatives when it enacted the Federal Food, Drug and Cosmetic Act in 1938, and amended its factory inspection provisions in 1953 and 1962. It could have imposed *primary* responsibility for the safety and wholesomeness of food products, and the truthfulness of food labeling, upon either the federal government or the individual food manufacturer. Faced with this choice, Congress concluded to impose it upon the manufacturer rather than upon the government. Under the present statute, it is the individual manu-

facturer who must initially interpret the statute, and apply it to his own product and problems, to determine compliance with the law.

At the same time, Congress concluded that there should be a governmental watchdog to make certain that the manufacturer in fact does comply with the law. The Food and Drug Administration (FDA) therefore was given the *secondary* responsibility of overseeing the manufacturers' actions and conclusions.

Perhaps the best way to illustrate the differences between the statutory functions of the individual food manufacturer and the government is to use the analogy of the traffic laws. The primary responsibility for the proper operation of a motor vehicle rests with the driver, not with the policeman. The policeman has neither the duty nor the right to instruct the driver how to operate his car. If the driver is found operating it improperly, the policeman has recourse to an informal reprimand or a summons to court.

The right of a manufacturer to run his own business in accordance with his interpretation of the statute carries with it an equally heavy duty. That duty is to take every reasonable measure to make certain that the public is neither harmed by food products nor misled by their labeling.

In enacting and amending the present law, Congress necessarily placed strong reliance upon the ability and willingness of food manufacturers to undertake this responsibility. There is no requirement of product licensing or continuous factory inspection. There is no requirement that FDA be given complaint files or quality control information or formulas or other data of this type. Congress made a determination that the food industry could be trusted to take whatever action is appropriate to protect the public health without these forms of close governmental supervision.

Congress also determined, in enacting the present statute, that the FDA could be entrusted with the equally heavy duty of policing industry's efforts within the guidelines set down in that statute. Congress drew a balance between no factory inspection and unlimited factory inspection, and concluded that the procedures set out in Section 704 of the Act are sufficient to carry out public policy. It undoubtedly relied upon the reputation of the FDA for fairness and effectiveness in drawing this balance and assigning this responsibility.

I believe that the vast majority of food manufacturers and government inspectors live up to these high trusts. There are, of course, a few manufacturers and a few inspectors who are not willing to meet the highest standards. In my judgment, this cannot be used as an excuse to undermine the public confidence in either the public or the private sphere. Nor can it be used to justify adoption of stiff requirements for all manufacturers or all inspectors when they are needed for only a few.

Industry's Constructive Attitude

Of course, even the most responsible manufacturer will at times experience problems, just as governmental organizations experience problems. Perfection has not yet arrived in either sphere, and as long as we are all human it is highly doubtful that it will arrive. Admiral Rickover has pointed out that:

> Advertisements and statements claiming that the particular organization has an effective "zero defect" program should be recognized for what they are—"motherhood" and propaganda statements.
>
> These are the sort of words administrators who have little or no technical competence love to use; they tend to delude the workers and customers as well as those who make the claim. In this way, they detract from meaningful effort.

Admiral Rickover suggests that anyone who relies upon such slogans, whether he is a regulator or a member of the regulated industry, should "be made responsible for personally directing in detail one of his projects" so that he can begin to understand "the human and material pitfalls involved." Some failure is inevitable, whether one relies upon a governmental agency or upon private individuals.

Full and effective cooperation must begin with an appreciation of Admiral Rickover's thesis. This appreciation must, moreover, be reflected in the public as well as the private pronouncements both of industry and of government. It matters little that the parties to this cooperative enterprise privately work together, if each publicly questions the other's competence and principles.

I believe that industry has come a long way in the past few years in understanding its limitations and in searching for new means to protect the public by assuring more wholesome foods. There is a growing awareness of problems, a willingness publicly to admit their existence, and an increased desire to solve them.

I have been disappointed in the apparent failure of FDA publicly to recognize this constructive attitude in industry. One

rarely reads a speech by a government regulator without finding at least one unfortunate reference to what is characterized as an unwillingness of industry to cooperate on factory inspection and an inability of industry adequately to protect the public interest. Conversely, in no speech by a government official have I seen a forthright and candid admission that government regulation is not infallible, that government inspectors sometimes overreach themselves, and that the source of all virtue and wisdom and knowledge is not necessarily a government official. Unless and until there is a willingness on the part of government officials to meet the regulated industry halfway, and to help build up consumer confidence in what is obviously the most wholesome food supply in the world, the current cold war will not abate.

Symptomatic of this problem, I believe, is Form FD-481 distributed in August 1967 by the FDA to its field inspectors. A list at the bottom of this form sets out some ten different types of so-called "inspection refusals." None of these "inspection refusals" necessarily involves a violation of the law. A food manufacturer may obey every last provision in Section 704 of the Act and still be pronounced guilty of an inspection refusal by the government. His food may be wholesome, his factory spotless, his labels letter perfect and his reputation impeccable. But if he chooses to rely upon his own competence in running his own business—as the statute provides he should—rather than to abdicate that function to the federal government, he will be condemned out of hand.

I find the inspection refusal entry on Form FD-481 highly objectionable. I can readily understand industry rebelling against this type of administrative overreaching. Any responsible citizen would take the same position. I hope that it will promptly be deleted from the form.

It is clear that industry is not interested simply in obstructing factory inspection. Any doubt about this has been dispelled by the fact that industry has permitted factory inspection to continue without search warrants, although recent Supreme Court decisions allow a manufacturer to refuse entry to inspectors without a warrant. And it is equally clear that the government is not interested simply in harassing industry. Recent working conferences demonstrate a willingness on the part of the government to pitch in to attack basic problems in a meaningful way.

Governmental self-restraint is, of course, not a popular concept today. Political reputations are not made by quiet action and soft persuasion, but rather by dramatic headlines. But if the public interest is to be served to the fullest extent possible, a way must be found once again to concentrate on the fundamental purpose of the Act—protection of the public.

In summary, it appears that industry and government both have their strengths and weaknesses. Indeed, the two appear about evenly matched. Neither can objectively claim an edge in intelligence, honesty, dedication, truth or justice. Industry appears at this time to be more candid in admitting its faults, but perhaps the government will catch up in this area as it achieves greater security and maturity.

[The End]

CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS PROPOSED FOR FOOD INDUSTRY

The Commissioner of Food and Drugs has proposed regulations to establish sanitation standards as "current good manufacturing practice" in the manufacture, processing, packing or holding of human foods. Comments on the proposals may be submitted by interested persons through January 14, 1968.

Included among the general requirements covered by detailed provisions are the following:

Grounds must be adequately drained and kept free of excessive dust and conditions favorable to rodents, insects or other pests.

Plants must be designed and constructed to facilitate proper maintenance and operation. Sufficient space and separation of areas must be provided, and lighting, ventilation, employee facilities and screening must be adequate.

Equipment and utensils must be so made and maintained as to preclude contamination and facilitate cleaning.

Adequate sanitary facilities must include proper water supply, plumbing, washing and toilet facilities, and sewage and rubbish disposal.

Operations must provide for proper maintenance, animal and vermin control, and cleanliness, sanitization and protective storage of equipment and utensils.

All operations connected with the processing of food, from receipt of raw materials through transport of finished products must be conducted in accordance with adequate sanitation principles under supervision of a person responsible for over-all sanitation.

Personnel practices must provide for disease control, cleanliness and training.

The proposed regulations were published December 15, 1967 (32 *Federal Register* 17980). The FDA has announced that there will be a series of appendices covering specific industries and problems.

Voluntary Compliance

By B. F. DAUBERT

Mr. Daubert Is the Director of Nutrition
at the General Foods Corporation.

GENERAL FOODS CORPORATION and the Food and Drug Administration (FDA) began a joint program in September 1967 to test the concept of an industry self-certification plan for quality assurance under a voluntary compliance program.

Many people have asked us why General Foods took this step. "What's in it for General Foods? It looks like it's all to the benefit of the FDA." I'll tell you why by quoting the Chairman of General Foods. Here's what he said: "It results in a common commitment to the concept of better protection for the consumer."

The general idea of voluntary self-regulation was advanced in the 1962 report to the Secretary of Health, Education and Welfare on the FDA by the Citizens Advisory Committee. This committee concluded that the government could never employ sufficient personnel to place an inspector in every food plant. The time has come, said the committee, for a more constructive approach to the problems of consumer protection. Reliable surveillance must be sought by encouraging industry to assume its share in the regulatory process.

The committee's report stated that self-inspection was a successful tried and proven approach. For example, the high standards in the salmon packing industry are due to close cooperation between the industry and the FDA.

Then in 1965, an FDA official said that one of the Agency's goals was to encourage and assist industry toward self-regulation. The target was to have one hundred percent coverage of the food, drug and cosmetic industries by 1970.

Now the ultimate aim of the joint study by the FDA and General Foods is to achieve better protection for the consumer in the areas of health, sanitation and economic risks.

At this point let me stress that we're talking only about consumer protection: protection mainly against health hazards and economic adulteration. I want to emphasize that this pilot study does not cover consumer satisfaction attributes. It does not concern itself with such things as flavor, taste, texture or coloring. For example, if a consumer complains about becoming ill after eating one of the products covered by the pilot study, we will inform the FDA immediately. But if a consumer complains that her dessert did not jell properly or did not taste right, we will not confer with the FDA on this.

The pilot study covers only two of our products: Jell-O Gelatin Desserts and Jell-O Golden Egg Custard Mix. Jell-O Gelatin Desserts represent a "non-critical" type product: that is, one in which the potential health hazard to the consumer is minimal. The Jell-O Golden Egg Custard Mix represents a "critical" type product. This is one in which the potential health hazard to the consumer is significant because of the presence of nonfat dry milk and dried eggs in the product. These two ingredients have the potential for being contaminated with Salmonella.

Long before the idea of this pilot study was born, we had developed comprehensive quality assurance programs for these two products, as well as for all of our products. When self-certification became a possibility, we spent four months working with the FDA to develop an initial self-compliance system that was acceptable to both parties. The system is designed to give us maximum assurance that the product meets all of the standards we both agreed upon.

I would like to emphasize that every item in the self-certification study is something we would do even if there were no voluntary compliance program under consideration. Self-certification will mean that when our quality assurance program shows up a variance from the standards, we will inform the FDA.

The self-certification systems we are studying with FDA spell out the frequency of ingredient sampling, the methods of sampling and the types of action to be taken when tests show that something does not measure up to the standards.

Let me point out that the discussion and development of these control systems between government and industry was in itself a positive experience. It permitted an open exchange of viewpoints between both parties. It also cleared up unresolved issues and possible areas of misunderstanding.

As we all know, when we want to control any product with absolute certainty, we need an infinite number of control points. But for self-certification to be practical from both the industry's and government's point of view, it is essential to determine the minimum number of control points that will give reasonable assurance that the product meets the standards upon which both groups agree.

There is always a temptation to set up a system that will call for more controls than are necessary. In our joint study with the FDA, we are attempting to arrive at a good marriage of practicality with reasonable assurance.

Both General Foods and the FDA agree that the initial plan which we established is probably too complex. But we feel that we had to begin in this fashion in order to develop a perspective which will enable us to properly select the most adequate controls. One of the objectives of this feasibility study will be to select those essential control elements which will have the greatest impact on achieving assured protection for the consumer.

By now, you can see that self-certification means that industry and government share information. So, monthly reports will be sent to the district FDA office, indicating variances from the plan. And all records relating to the control system will be made available to the Agency during plant visits. As far as formulas are concerned, we give the FDA a list of ingredients—but we do not give the amount of each ingredient in a product.

Obviously, the amount of paper work generated in any such system gets bigger as the system gets more complex. Too many controls would mean that the essential information would get buried in a mass of details. So, when we finally reduce the number of controls to the minimum, we will get rid of a lot of paper work.

While this joint study is now set to cover a one-year period, we are sufficiently enthusiastic to believe that we will be able to eliminate a good many of the control points in our present control system sooner than the target date. Within six months, we should be ready

to begin the necessary program to place all of the products we make at our Jell-O plant under a self-certification plan.

Obstacles to Industry Self-Regulation

Now let's turn to some of the obstacles that could stand in the way of industry self-regulation. We see three: people, impracticality, and inflexibility.

First of all, you need people in both groups who will try hard to make self-regulation work. You need people who believe in the concept. I think we all have to admit that there will be people in industry, as well as government, who will not be personally motivated to make self-compliance work properly. But we think that this obstacle can be overcome by the common self-interest both the FDA and industry have in developing a workable self-regulation program. As the Citizens Advisory Committee pointed out, an industry self-compliance program will "lessen the FDA's regulatory problems considerably, leaving it much more time for more important activities." Industry will benefit by having regulations that will be reasonable—that is, regulations that will avoid exhorbitant costs or costs that might tend to drive a product off the market. Both parties benefit by assuring better protection for the consumer. During this feasibility study we hope to single out the high priority items that assure such protection. We cannot attempt to protect against each and every eventuality. The system has to be practical.

Another obstacle is inflexibility. The system must be easy to change without a great deal of red tape and formality. The system should not hamper or discourage changes in a product to allow variations for the consumer's choice.

The system should not become so rigid, so inflexible, so ingrained that it is almost impossible to use new technology or advancing methodology. To live, industry must progress, and the concept of self-regulation cannot stand in the way of progress.

Let me emphasize, if industry ends up doing things it does not believe in, just to please the FDA, there is no good basis for a working relationship.

Future of Industry Self-Regulation

Now let's take a look into the future of industry self-regulation. As I mentioned earlier, the FDA in 1965 stated that it was aiming

at one hundred percent self-regulation of the food industry by 1970. Certainly we would have to agree that self-regulation is the best way by which industry can keep its own house in order.

Again, as the Citizens Advisory Committee said, the government simply could not place an inspector in each and every food plant in the nation. Industry self-regulation, therefore, has to be the answer to assuring consumer protection. The Committee pointed out that such a course of action would free FDA inspectors to supervise problem areas where they are most needed. It will also create a feeling of cooperation and respect among the many ethical producers who honestly desire to produce the best possible product and to serve the public interest.

Wouldn't we all agree that continuous in-plant inspection by each company would be more efficient than a stepped-up series of inspections by the FDA? As the Advisory Committee said: "Once suitable control standards have been established, the inspection activities of the FDA should be largely devoted to measurement of the adequacy with which industry maintains these standards, except for intensive investigation of firms which fail to meet the standards or which employ operating methods contrary to the standards."

It is obvious to us that the close cooperation between a company and the FDA—which is necessary to agree on a self-regulation program—produces common understanding, trust and respect. It certainly should reduce drastic action being taken on violations and provide the opportunity for discussion before such action is taken.

Self-certification represents a significant thrust in constructively combining the talents and responsibilities of government and industry to achieve better protection for the consumer. It places a new and important responsibility on the FDA, which should be commended for its willingness to move in this direction. **[The End]**

CHANGE OF PERSONNEL IN THE FDA

Jack Bologna, formerly Director of the Bureau of Drug Abuse Control in Baltimore, Maryland, has been appointed Director of the Food and Drug Administration's New Orleans District. He succeeds Leslie O. McMillin, who was named Director of the Atlanta District. The New Orleans District includes the states of Louisiana, Mississippi, Alabama and western Tennessee.

Good Manufacturing Practice Regulations for the Food Industry

By GEORGE M. BURDITT

Mr. Burditt Is a Partner in the Law Firm of Chadwell, Keck, Kayser, Ruggles and McLaren and a Member of the Illinois Legislature.

FOR A NUMBER OF YEARS, the Federal Food & Drug Administration has considered the possibility of promulgating Good Manufacturing Practice (GMP) regulations for the food and drug industries. In 1962, Congress brought this idea one step closer to fruition in the Kefauver-Harris amendment adding to the Federal Food, Drug & Cosmetic Act, among other things, § 501(a)(2)(B) which provides that a drug shall be deemed to be adulterated if:

> The methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with *current good manufacturing practice* to assure that such drug meets the requirements of this Act as to the safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . . (Emphasis added.)

Since the statute does not spell out what is meant by "current good manufacturing practice," FDA has promulgated GMP regulations relating to finished pharmaceuticals (21 C.F.R. § 133.2 to 133.14)[1], and medicated feeds (21 C.F.R. § 133.100 to 133.110)[2]. In addition, GMP regulations governing medicated premixes have been proposed, with an effective date of December 31, 1967 (21 C.F.R. § 133.200 to 133.210)[3].

[1] CCH Food Drug Cosmetic Law Reports ¶ 72,102—72,114.

[2] CCH Food Drug Cosmetic Law Reports ¶ 72,141—72,151.

[3] CCH Food Drug Cosmetic Law Reports ¶ 72,181—72,191.

Since most of us are concerned with food, and since the food industry hasn't had much to do with GMP regulations, perhaps I should briefly summarize the regulations which cover finished pharmaceuticals. Different subsections of these regulations cover the drug manufacturers' buildings, equipment, personnel, components of the drugs, master-formula and batch-production records, production and control procedures, product containers, packaging and labeling, laboratory controls, distribution records, stability of drugs, and complaint files. Under each of these subsections, details are given as to what is expected of drug manufacturers in order to comply with the GMP regulations. For example, equipment must be maintained in a clean and orderly manner and must be of suitable design, size, construction and location in relating to surroundings to facilitate maintenance and operation for its intended purpose. It must be so constructed that any surfaces that come into contact with drugs do not react with, add to or absorb from drugs, must be so constructed that any substances required for the operation of the equipment may be employed without risk of contaminating the drugs, must be so constructed as to facilitate adjustment, cleaning and maintenance to assure uniformity of production and exclusion of contaminants, and must be of suitable size and accuracy for use in any intended measuring, mixing or weighing operations. Similar detailed provisions cover each of the various items which is the subject of one of the subsections of the finished pharmaceutical GMP regulations.

This background on GMP regulations for the drug industry is an important precedent for GMP regulations for the food industry. We can expect detailed guidelines covering the food manufacturers' buildings, equipment, personnel, and all other matters which are essential to the manufacture of a clean and wholesome food supply.

Food GMP Regulations

FDA has announced its intention to promulgate "umbrella" type regulations covering the entire food industry in general terms. I understand that a draft of these "umbrella" regulations has already been circulated to the FDA district offices for comment, but is still not available for general distribution. The "umbrella" regulations will be supplemented by regulations covering specific industries, and of course going into more detail on problems in those industries. FDA has already published GMP guidelines for processors of animal, fish and

poultry by-products, for nonfat dry milk, for dried yeast, and for smoked fish. So GMP regulations for the food industry are really a two-step process: a general regulation covering all food establishments, and specific regulations covering various segments of the industry.

Statutory Authority

§ 701 of the Act provides that: "The authority to promulgate regulations for the efficient enforcement of this Act . . . is hereby vested in the Secretary." This would appear to be adequate to justify both drug and food GMP regulations. But there is one difference between *drug* GMPs and *food* GMPs in so far as statutory authority is concerned: § 402 of the Federal Food, Drug & Cosmetic Act, the adulterated food section, unlike its drug counterpart § 501, does not mention "current good manufacturing practice [CGMP]." The Kefauver-Harris amendment relates solely to drugs. Therefore, the authority to promulgate food GMPs rests on the more general provisions of § 402(a)(4) which provides that a food shall be deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions . . ." Query whether this difference in wording, when coupled with the legislative history of the two sections, has any legal significance.

Legal Effect of Food GMP Regulations

A question which must be foremost in the minds of industry and FDA is the legal effect of food GMPs. Will FDA consider every failure to comply with the food GMPs to be a violation of the Act? Will the courts sustain such a position? On the other hand, will food GMPs serve any constructive purpose *unless* a failure to comply constitutes a violation of the Act?

The specific GMPs which have already been published for nonfat dry milk and the other items I mentioned a moment ago are all entitled "Guidelines." A guideline would not normally be considered to have the force and effect of law. Query whether the general food GMPs, and future specific GMPs, will also be "guidelines," and if so how FDA and the courts will treat a failure to comply.

Looking to the drug GMPs for precedent, FDA does consider a failure to comply to be violation; Mr. Barnard said back in June at the meeting of the Association of Food and Drug Officials of the United States in St. Paul that

. . . Congress passed the Kefauver-Harris Amendments with a provision which, in effect, states that a drug shall be deemed to be adulterated if it has been manufactured under conditions which do not accord to CGMP.

I assume that Mr. Barnard would take the same position with regard to food GMPs. FDA has been most helpful in assisting industry to comply with the drug GMPs, and has not followed the procedure of bringing legal action for every minor oversight, provided it is being corrected.

I should also point out that the statute does not require a hearing before FDA can promulgate GMP regulations, although FDA has customarily afforded an opportunity for comment. This also may have a bearing on FDA's enforcement policy, and also on the legal effect of a failure to comply with the GMPs. The mere existence of the GMPs, however, with the possibility of strict technical enforcement by FDA, has a far reaching practical effect, regardless of the legal effect.

Pros and Cons

As a prelude to some meaningful discussion here this afternoon, perhaps I should outline some of the pros and cons of GMP regulations for the food industry.

Some of the arguments in favor of food GMPs are:

(1) Sanitary and quality standards will be raised;

(2) All segments of industry, particularly smaller concerns, will have the advantage of the expertise of governmental and industry officials which goes into the preparation of such regulations;

(3) Industry will have the advantage of being able to read specifically what is required in terms of buildings, equipment, personnel qualifications, record-keeping, and all of the many other subjects which will be covered in both the general and specific regulations;

(4) Consumers will benefit by having further assurance that good manufacturing practices are being followed by all firms which ship food in interstate commerce;

(5) Uniform requirements, interpretation and enforcement will exist among the various district offices of the Food & Drug Administration; and

(6) State officials, who necessarily do not have the same facilities and expertise available to them as does the Federal Food & Drug Administration, will be able to follow the GMP regulations in their states so that food shipped only in intrastate commerce can also benefit indirectly from the federal regulations.

Some of the reasons for going slow on Good Manufacturing Practice regulations for the food industry are:

(1) GMP regulations are another example of unnecessary government regulation of our already overregulated food industry;

(2) Food GMPs may be guidelines at the outset, but almost inevitably they will become mandatory, in which case a manufacturer will be guilty of violating § 402(a)(4) of the Act, and will be subject to criminal prosecution, injunction, and seizure of his goods, if he fails to comply with regulations on which he wasn't even entitled to a hearing;

(3) The GMPs will inevitably be either so strict that many firms, particularly smaller ones, will be unable to comply and will have to go out of business, or so general that they will be meaningless to most firms; and

(4) Is the consumer ready to accept still higher food prices which would inevitably result if manufacturers are required to make substantial changes in their plant, equipment, etc.?

Regardless of the pros and cons, it is apparent that the food industry is going to have GMP regulations in the very near future. Close cooperation among the triumvirate of consumers, industry and FDA is essential in order to develop meaningful regulations which will give further assurance of a safe and wholesome food supply. **[The End]**

REORGANIZATION IN THREE FDA OFFICES

The reorganization of several offices in the Food and Drug Administration has been announced. The Office of Drug Surveillance of the Bureau of Medicine has been replaced by the Office of Marketed Drugs. A new Office of Medical Support has been added which includes the Divisions of Drug Experience, Medical Advertising, Research and Liaison, Scientific Investigations and Statistics. The Office of Medical Review now includes the new Divisions of Clinical Devices and Hazardous Devices.

FDA's Voluntary Compliance Program

By JOHN A. KEDZIOR

Mr. Kedzior Is a Member of the Bureau of Education and Voluntary Compliance of the FDA.

I AM VERY PLEASED to have this opportunity to discuss the Food and Drug Administration's (FDA) current and future plans in what we consider to be a close partnership with industry. Of course, I am referring to the voluntary compliance programs. If we have hopes and aspirations for participating in the program we must have a sincere desire and show a positive effort to assume the responsibility our form of government has placed on us.

At this point it is appropriate to mention a comment made by Secretary Gardner at the dedication of the FDA building:

> The protection of the public calls for a vast collaborative effort. We intend to play our role in that collaboration. And we are going to expect others to play their role. * * *
>
> Democracy puts a great burden on the individual and non-governmental institutions. We expect the individuals and institutions of a free society to behave responsibly. In short, regulation in a free society puts a heavy burden of responsibility on the industry or enterprise which is regulated. Only when that responsibility is neglected does enforcement in a punitive sense become necessary.
>
> Make no mistake about it—we will not hesitate to use the authority given to us to protect the public health. However, every time this becomes necessary, it represents a failure of the cooperative enterprise we value so highly.

You have often heard the statement, "The spirit of the law is best served through a balanced program of enforcement and education." We in FDA firmly believe this to be the best approach, and based on your responses to our voluntary compliance programs, we are convinced you do also. The Administration, both at headquarters and at the district level, carries on programs intended to help members of

the food industry understand what is expected of them under the Act, and to provide assistance in solving any problems they encounter in fulfilling these obligations.

FDA is stressing voluntary compliance more than it has ever done before and this requires cooperation with industry, that is, meeting on a common ground and working toward a common goal of product integrity and quality assurance. The door is always open for frank and open discussions with industry on their problems. We don't know all the answers and you don't know all the answers, but possibly together we can attack, and work out solutions to, most of the compliance problems. We must come to grips with these problems for they will not vanish or go away of their own accord. Now let us turn to FDA's voluntary compliance program.

During the 1964 reorganization of FDA, the Bureau of Education and Voluntary Compliance was established on recommendation of the 1962 Citizen's Advisory Committee. It was given equal status with the other five Bureaus of the FDA. The end result of this was the setting up in FDA of a Voluntary Compliance Program aimed at effectively providing industry with facts and techniques that will give industry the greatest opportunity to comply with FDA regulations and standards. Each of FDA's 17 Field Districts and all FDA units participate in this voluntary compliance program. Translated into terms of practical action, this means:

(1) that FDA will do everything it can to provide advisory assistance and information to industry;

(2) that FDA will endeavor to reach each regulated industry with an explanation of how the laws and regulations affect it;

(3) that FDA will make available to industry results of our scientific research and improved analytical methodology; and

(4) that FDA will make recommendations to industry for controlling bacterial or chemical contamination and for good sanitation practices.

To accomplish this requires good communications. Among the most effective communication tools, we find workshops and seminars with industry to offer the greatest incentive for exchanging views and solving problems.

In 1967 industry participated in 70 workshops involving bacterial and chemical contamination and sanitation. These were sponsored by

our 17 Field Districts in cooperation with industry associations. An estimated 2,000 food firms were represented among the 6,200 industry attendees. In fiscal year 1968 we plan to participate in 100 to 125 similar workshops for the food industry. Dates and places of tentative and scheduled workshops are listed on the back of each issue of *FDA Papers.*

The workshop program is only the beginning of our efforts to provide industry with additional tools to aid them on the road to voluntary compliance. In the near future we plan to develop industry training programs dealing with inspectional techniques, analytical procedures and instrumentation. In this effort we will look to industry to assist us in identifying areas of greatest need in developing training guides. We would very much prefer that industry through their associations, and working in close harmony with FDA, develop programs along these lines wherever they can. In addition we plan to explore the academic curricula for courses which will benefit industry personnel in inspectional or analytical expertise. Through these training aids we envision that plants will then be on a firmer footing to undertake meaningful and effective self inspection and quality assurance programs.

To assist you, we have prepared fact sheets on bacteria types, and the first of a series of slide shows. These materials have a non-technical approach. A slide series on bacterial contamination in food and on antibiotic residues in livestock is in its initial steps of preparation at our headquarters in Washington. We are also developing separate posters containing guidelines for employees when receiving, processing and storing food products. When available, these aids should be useful for training food-plant employees.

FDA is also preparing "Umbrella" good manufacturing practice guidelines. These will contain basic sanitation requirements and will be issued in the form of regulations. However, it is recommended that you do not wait until they become available, for it may take some time. Instead, it is highly recommended that you take the initiative and prepare your own. If help is needed with the self-regulation programs, contact the nearest FDA District Office. Providing consumers with safe, wholesome food products is our joint responsibility and is a common goal we all share. **[The End]**

INDEX

VOLUME 22 1967

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