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Food Drug Cosmetic Law JOURNAL

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

Papers Presented at the 1967 Annual Meeting of the New York State Bar Association Section on Food, Drug and Cosmetic Law

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

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

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FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . February, 1967

VOLUME 22 NUMBER 2

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

1966 FDA-FDLI Conference.—The concluding papers presented at the Tenth Annual Joint Conference of the Food and Drug Administration and the Food and Drug Law Institute are included in this issue of the JOURNAL. Previous papers presented at the Conference were in the January, 1967 issue.

"Report From FDA," which begins on page 68, is by *Dr. James L. Goddard,* Commissioner of Food and Drugs. The Commissioner discusses the increasing areas of cooperation among federal, state and local agencies to provide consumer protection, and he urges industry to join in the partnership.

"International Food Standards: Status Report," commencing on page 75, summarizes reports given at the Fourth Session of the FAO/WHO Codex Alimentarius Commission. The author, *George R. Grange,* is Deputy Administrator of Marketing Services in the Department of Agriculture.

In "'GMP' as an Answer to Drug Recalls," *Douglas C. Hansen,* Director of the Division of Program Operations of the FDA, states that Good Manufacturing Practices can reverse the upward trend in required recalls. The article begins on page 79.

"Assuring Drug Integrity—New Challenges, New Horizons," starting on page 85, complements the preceding "GMP" article with an outline of the drug industry's efforts to achieve assured product quality. *Dr. L. Paul Sinotte,* Director of Quality Control for Merck Sharp & Dohme, lists the "dynamic imperatives" required.

Twenty-Second Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association.—The introduction and four of the papers presented at the meeting are featured in this issue of the JOURNAL. Additional papers read at the meeting, which was held in New York City on January 24, 1967, will be published in a later issue.

The brief "Introductory Statement" on page 91 is by *Franklin M. Depew,* President of the Food and Drug Law Institute and Chairman of the meeting.

Dr. James L. Goddard, Commissioner of Food and Drugs, makes a second appearance in this issue with "The Year in Review," beginning on page 92.

In "Reflections on Food Standards," which commences on page 100, *Vincent A. Kleinfeld* criticizes present food standards and food standard procedures and makes recommendations for improvements. The author is a member of Bernstein, Kleinfeld & Alper.

Michael F. Markel, a member of Markel & Hill, in "Foods for Special Dietary Uses—An Historical Outline of Regulatory Aspects," beginning on page 110, reviews aspects of the 1940 hearing which led to early regulations, as a background for present issues.

"Product Liability—1966," starting on page 125, discusses the increasing acceptance by the states of the doctrine of strict liability in tort. The author, *William J. Condon,* attorney for Swift & Co., has also provided a list of 1966 product liability cases, grouped by classification.

The President's Message on Protection of the Consumer.—Excerpts from President Johnson's message to Congress appear on page 132.

Vol. 22, No. 2 February, 1967

Food·Drug·Cosmetic Law
Journal

Report From FDA

By JAMES L. GODDARD, M.D.

The Following Report Was Presented at the Food and Drug Law Institute—Food and Drug Administration Tenth Annual Educational Conference at Washington, D.C., on November 28, 1966. Dr. Goddard is Commissioner of Food and Drugs. The Three Succeeding Articles in This Issue Were Presented at the Same Conference.

THE FOOD AND DRUG ADMINISTRATION (FDA) always has welcomed this joint conference, which has been conducted every year for a decade now. This series of meetings has demonstrated the fruitfulness of open discussion between those of us who represent government, those who represent industry, and those who are apart from, but keenly interested in, the activities and problems of both.

As many of you know, the FDA has been sponsoring an increasing number of conferences, seminars, workshops, and the like with various industry groups. This illustrates our conviction that these joint discussions are valuable—as well as our hope that better communications will give birth to improved Government-industry cooperation on a day-to-day basis.

I take it for granted that we all share the view that the public interest, which all of us must serve, demands the highest degree of cooperation. And it is the broader ramifications of this theme that I want to discuss with you.

As all of you are aware, consumer protection is the business of all the nation. It is not a program that concerns only a handful of officials here in Washington and this industry and that industry whose products come within the scope of the Federal Food, Drug and Cos-

metic Act. No, state governments and local governments also have important responsibilities in this area. And cooperative programs which involve these different levels of government are as necessary as cooperation between government and industry.

President Johnson holds this view, certainly. He has said:

"The task of protecting the consumer cannot and should not be left solely to the Federal Government. The Government can and should provide creative Federal leadership to help States and local communities in their own constructive and determined efforts."

The staff of the FDA is fully aware that our own agency cannot by itself carry out the life-protection programs that are essential today. We must work with state and local officials, and we do. Those officials are vital partners in the enforcement of food and drug laws. Their agencies play as prominent a role as any federal agency in protecting the health of this nation. And state and local agencies, working with FDA District Offices, can help the food, drug and cosmetic industries not only meet the obligations of the law and regulations, but grow and thrive in the process.

This kind of partnership has never been more important than it is today. Our society has grown more complex in every way and this transformation has embraced the marketplace, too. Many of you are more aware of this than I. At the same time, the consumer has become more sophisticated, more alert to environmental hazards which are in many cases man's own creation, and more aggressive in demanding effective protection.

The Congress and the legislatures of many states have responded to this demand. At the national level, a number of new responsibilities have been placed upon the FDA in recent years. And this, in turn, has increased the need for meaningful cooperation between federal, state, and local agencies in meeting these responsibilities.

Drug Abuse Legislation

The Drug Abuse Control Amendments enacted last year provide an apt example. As you know, the purpose of this legislation is to attack the illicit traffic in the amphetamines—the "pep pills"—and the barbiturates—the "goof balls"—and other drugs that are particularly subject to abuse.

The Amendments gave stronger enforcement powers to the FDA to deal with the producers and peddlers engaged in this illegal, and despicable, traffic in abusive drugs. And the FDA moved promptly to implement this new authority. The Bureau of Drug Abuse was

organized and staffed. Agents were recruited and trained and more than 200 of them are now working out of nine field offices around the country.

But one of the key provisions of the law was that those who make and dispense these drugs must keep accurate and complete records on their movement from the manufacturing plant to final sale to the retail customer. These records are vital in order to track down—and close down—the sources of the illicit drug supply. Laws and regulations are rather meaningless, however, unless there are means of assuring compliance. The Drug Abuse Control Amendments imposed record-keeping requirements, not only on the manufacturers and distributors of the covered drugs, but on some 54,000 retail drug stores that dispense them.

Obviously, the FDA does not have sufficient staff to provide any kind of comprehensive inspection program for a task of that magnitude. And we do not anticipate having a staff of that size. Instead, we have turned to the states for help. And we are getting it. We have developed a pilot program under which six states are monitoring compliance with the Drug Abuse Control Amendments at the retail level, while federal agents are giving primary attention to wholesale drug distribution. Florida, Georgia, Indiana, New York, Texas, and Washington are the states participating in this program now. We hope that other states will be included later. And the success of the pilot program indicates that this hope will be realized.

Our Bureau of Drug Abuse Control has held conferences with the state officials concerned with this program to develop the close working relationship that is essential for its success. The Bureau also is sponsoring conferences with law enforcement agencies in a number of states. State laws also deal with illegal drug sales and this is another element of the federal-state partnership to deal with a common problem.

State colleges of pharmacy and other education agencies, as well as state licensing boards, also have demonstrated a willingness to support the attack on drug abuse and a desire to cooperate in every way possible. This is as it should be. We expect continuing development of the intergovernment relationships in this field.

Other Areas of Cooperation

There are many other areas where the cooperation of government agencies at all levels is no less essential. And the FDA is determined

to provide leadership and support in every way possible to strengthen consumer-protection programs through this kind of cooperation.

More than 2,000 state and local officials, for example, have participated in FDA-sponsored courses in food inspection techniques. This is a vital area, certainly, for the problem of food sanitation is nowhere near solution as yet. In this country, we are able to send vehicles into space that are practically germ-free, but we are not always able to provide adequate sanitation for the food we eat.

The fact that Salmonella contamination of food was a major topic at this conference indicates that we have far to go in dealing with this problem. The same is true of contamination by staphylococcus and botulinus. The fact that food-borne diseases continue to be a significant national problem indicates there must be an intensified effort in food sanitation by all agencies concerned—federal, state, and local. And the food industry, obviously, must take the steps that are necessary to prevent contamination and accept the help that well-trained inspectors can give in correcting deficiencies.

Let me mention one other example of the stronger federal-state partnership that is being forged to serve the consumer more effectively. Thirteen states—from Maine to New Mexico—are now sharing with the FDA the responsibility of inspecting medicated feed plants. Here again is an instance in which a new process, a new use of drugs, imposed a new function upon the FDA. Until recent years, there were no medicated feeds. But then came the discovery that feeds were an effective vehicle for drugs that promote growth or prevent disease in food animals. There are now thousands of mills across the country that mix medicated feeds. Regular inspection is necessary since the process of mixing a minute quantity of a drug with tons of feed is new to the mills, too. State assistance is invaluable in this respect. I might add that the Federal Government also is providing training in this area. Courses in medicated feed inspection were offered this year in Harrisonburg, Virginia, and Dover, Delaware. The course also will be given in Sacramento, California, and Madison, Wisconsin.

There are many other types of cooperation, of course. The FDA provides prompt support for state and local agencies when problems arise that require assistance. And state and local agencies have provided assistance, in turn, in monitoring recalls. We also draw upon the expertise of those agencies in dealing with such problems as botulism.

We also are developing a wholly new system for commissioning local officials to conduct certain examinations and inspections as provided in the federal Food, Drug and Cosmetic Act. The commissioning procedure has been generally useful in the past, but at times state and local officials were empowered to carry out investigations for which they were not trained. Last June, all of the outstanding commissions were cancelled so that we might put this program on a sounder basis.

I think we can do more, much more, to increase the potential of this federal, state, and local partnership in carrying out the consumer-protection responsibilities that we share.

Co-ordination in Training Personnel

You may recall the recommendations of the Public Administration Service submitted to the FDA early in 1965. Among the recommendations was one on personnel, which said:

"Although there is much that State and local agencies and universities can do for themselves and for each other, important advances in the area of training can be better achieved by a coordinated national effort. A concerted effort to overcome training deficiencies is a necessary element of a needed operational coordination that combines Federal, State, and local efforts. Advantages of such coordinated planning for training of food and drug workers across the country are clear."

I have mentioned examples of the training which the FDA now provides for state and local food and drug officials. These training opportunities could be expanded many-fold, but one obstacle is the inability of many state agencies to cover the indirect costs of training, such as per diem and travel costs. The Public Service Administration recommended "effective subsidization" as a necessary part of a successful, coordinated national training program. Federal underwriting of these indirect costs would, in my opinion, be a sound investment in the national interest. We must make it possible for more state departments and state boards to take advantage of federal law enforcement or inspection training, of federal laboratory and research capabilities.

State and local officials, with improved and expanded training programs open to them, would carry back to their own assignments improved techniques and new information. Life-protection programs would be strengthened right at the local level. And enforcement activities would gain in consistency and effectiveness.

Flexibility and Efficiency

I strongly believe that our consumer-protection efforts must operate quickly and efficiently at the grass-roots level. As most of you probably know, one facet of the reorganization within the FDA provided greater decision-making authority at the District level. District Directors now report directly to the Office of the Commissioner, rather than to the Bureau of Regulatory Compliance. All of the headquarters bureaus of FDA now have equal access to our field offices. And the District Directors have direct access to my office.

The field directors will have greater flexibility, operating within policy guidelines rather than by consultation with headquarters on a case by case basis. And I believe the end result will be a quicker response to problems as they arise—and that means better protection for the consumer.

We also have studies underway which look toward greater efficiency in planning and conducting our field operations. I have already alluded to new responsibilities which Congress has placed upon the FDA. Apart from these, however, there has been a steady, and rapid, growth of responsibilities imposed by the expansion of FDA-regulated industries, an expansion in technology and techniques as well as in size. What is the best "mix" of inspectional activities to meet these responsibilities? What combination of skills is necessary to carry out these field programs most efficiently? How should our field personnel be deployed? These are the kinds of questions we are answering now.

The objective, of course, is to achieve the most effective utilization of manpower and skills and facilities to provide the maximum measure of protection to the consumer.

I have dwelled on the cooperative programs undertaken by the emerging federal-state-local partnership because I think it is important that we view problems such as those discussed today in the broadest possible context.

Consumer Protection: the Common Goal

Consumer protection, after all, is a single mission. There may be differences in food and drug laws from city to city, from state to state, and from state to federal. But the essential purpose, the common goal, is the protection of the health and welfare of our citizens everywhere.

In recent months, I have often urged a more productive partnership between government and industry in fulfilling our mutual responsibilities in the consumer interest. I have proposed that industry take a stronger initiative in developing appropriate means to protect the consumer interest through voluntary efforts.

I would suggest that industry also has an interest in—and should support—the steps now being taken to realize the great potential of a federal-state-local partnership in achieving an effective consumer protection program. Americans must rely on one another, now more than ever before. This interdependence is nowhere more important than in the field of health.

Only cooperation in the broadest sense of the word can help us overcome those problems which press upon us today—and those sure to arise tomorrow—so that we can succeed in our common mission: the protection of the health and life of every citizen in this Nation.

[The End]

FEASIBILITY OF NATIONAL DRUG TESTING CENTER BEING STUDIED

A pilot program to study the feasibility of a National Drug Testing Center is being undertaken by the FDA. "We have recognized the need to expand considerably our drug sampling and analysis program," said James L. Goddard, M.D., Commissioner of Food and Drugs. "Now, we want to see if this can best be accomplished by concentrating much of the analytic work in one central location." A national testing center would permit greater use of the sophisticated automated instrumentation development in recent years, Dr. Goddard explained. It also would further the development of more advanced instrumentation and procedures to facilitate drug testing.

The program will be started in St. Louis, Missouri, using existing facilities of the FDA's St. Louis District Offices. Scientific personnel already working in the St. Louis District Office will staff the drug testing center with additional personnel being brought into the center as necessary.

The program will be implemented on a gradual basis beginning in about one month. As the work load increases, analytic work normally handled in St. Louis will be shifted to the Kansas City District or other field laboratories.

Drugs in one or two therapeutic classes will be involved in the project, and all samples of drugs in the categories selected will be sent to St. Louis from other FDA districts.

The FDA now analyzes about 40,000 drug samples a year throughout the country. It is estimated that a well-equipped central laboratory could analyze 150,000 samples a year. In the pilot operation, however, the St. Louis laboratory will handle only a few thousand samples.

According to Dr. Goddard, each of the District Offices would continue to handle some drug analytic work even if a National Drug Testing Center were established on a permanent basis. This is because not all drug products lend themselves to automated analytic techniques.

International Food Standards: Status Report

By GEORGE R. GRANGE

Mr. Grange Is Deputy Administrator of Marketing Services with the Consumer and Marketing Service of the United States Department of Agriculture.

THE FOURTH SESSION of the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Codex Alimentarius Commission was held in Rome on November 7-14, 1966. The status of the work on international food standards can best be presented by summarizing the reports given at this session.

The purpose of Codex standards is to help both industrialized and developing countries. For industrialized countries exporting manufactured foods, the merit of a Codex standard would consist in the possibility of freer movement of foods from country to country. For developing countries, the merit of a Codex standard would be to help in the formation of food legislation and to provide adequate standards for consumer protection, as well as to assist in promoting exports.

The fourth session of the Commission was informed that thirty-nine member nations of FAO or WHO have formally registered their membership in the Codex Alimentarius Commission. Also, we were informed that formal declaration of membership is anticipated from fourteen additional countries.

Work on specific standards is conducted by the special Codex committees, most of which are organized on a commodity basis. There are four important committees, however, which are organized on a subject matter basis. These are the Committees on Food Additives, Food Hygiene, Food Labeling and Pesticide Residues.

A tentative timetable for committee meetings in 1967 was approved at the session. There are fourteen committee meetings scheduled, starting with the Fats and Oils Committee during April, 1967, and ending with the Milk Products Committee in January, 1968. The status of the work and the tentative plans for subjects to be discussed at each of the committee meetings to be held during 1967 were reviewed by the Commission.

Developmental Stages of Codex Standards

According to my rough count, approximately seventy-five different Codex standards are now in various stages of development. Let me describe some of these. A general code of hygienic practice has been sent to governments for comments. It will be considered at the 1967 meeting of the Hygiene Committee. A general standard for food labeling has been developed and circulated for comments. It will be reviewed and considered by the Labeling Committee at its meeting in Ottawa, Canada, next June. Tolerances for malathion and two other chemical compounds have been proposed by the Pesticide Residues Committee. The Cocoa and Chocolate Committee has drafted standards for eight different products, and the government comments received on these drafts will be considered at its 1967 meeting. The Fats and Oils Committee has developed draft standards for twelve products. In fact, all commercially important fats and oils have been covered by this committee, including soybean oil, cottonseed oil, lard and margarine. Emulsifiers, anti-oxidants and contaminants are discussed, and identity and quality characteristics are set forth in the proposed draft standards for these fats and oils.

In addition, there are numerous draft standards in various stages of development by the other Codex committees which cover meat, processed fruits and vegetables, fish, sugars, milk products, dietectic foods and fruit juices. In view of the large exports of honey, I should not omit the development by a special European committee of a proposed honey standard which is almost ready for final presentation to the Commission.

It is apparent that a lot of spadework has been done by the Codex committees. During the next couple of years, this work will result in final provisional standards being presented to the Commission, which, upon approving the standards, will transmit them to member nations for formal acceptance or rejection. It is at this stage that

such standards will have great significance for the United States. It is very important for everyone to realize that Codex standards can have a significant impact on both exports and imports. In order to appreciate this fact, it is necessary to have a clear understanding of the meaning of "acceptance" of a Codex standard.

The Significance of Acceptance

Formal acceptance of a Codex standard will, of course, be entirely discretionary or voluntary on the part of the U. S. Government or any other member nation. However, after a Codex standard is fully accepted by a government, a product—whether imported or home-produced—to which the standard applies will be permitted to be distributed freely within such country *only* if it complies with all the requirements of the standard. For example, if a provisional Codex standard provided for 110 ppm of biphenyl on citrus fruits, a country would be undertaking two obligations in accepting such standard. First, it would obligate itself not to interfere with the free movement of any citrus fruit—imported or home-produced—containing less than 110 ppm of biphenyl. Secondly, it would obligate itself to prohibit or otherwise restrict the free movement of citrus fruit—imported or home-produced—containing more than 110 ppm.

As you can see, the objective of a Codex standard is not simply to provide a voluntary guide for use in exporting. The objective is the much broader one of setting forth an internationally accepted minimum requirement which would be applied without discrimination by all member nations. In addition to full acceptance, the general principles of the Codex Alimentarius Commission provide for target acceptance of a standard after a stated number of years or acceptance of a standard with a declaration of more stringent requirements for certain specifications.

In addition to these three kinds (or degrees) of acceptance, a clarifying amendment was proposed by the Commission at this last session which would provide that if a country is unable to accept a Codex standard in any of the three ways given above, it should indicate: (a) whether products conforming to the standard may be distributed freely within its borders, (b) which provisions of the standard it is prepared to accept, and (c) in what ways its requirements differ from the standard. One objective of this proposed amendment to the acceptance procedure is to provide, when the Codex Alimentarius is published, full information concerning the specific requirements of

each country whenever they differ in whole or in part from an established Codex standard.

Role of the United States

It is abundantly clear that the United States has a great deal at stake, considering the effects on U. S. trade which could result from the acceptance of Codex standards by important exporting or importing nations who are actively participating in the development of these standards. We must give this matter our careful attention, therefore, and participate fully in the developmental work. Cooperation and assistance from the food and chemical industry is highly important if the United States' position is to be developed and presented as knowledgeably and effectively as the importance of the work warrants.

[The End]

RECENT ELECTIONS AND APPOINTMENTS ANNOUNCED

Franklin M. Depew, New York City, has been reelected to a seventh term as Chairman of the Food, Drug and Cosmetic Law Section of the New York State Bar Association at a meeting held in New York City on January 24, 1967, in conjunction with the 90th Annual Meeting of the State Bar. Also reelected were A. M. Gilbert, Vice Chairman, and Raymond D. McMurray, Secretary, both of New York City.

Reelected to the Section's Executive Committee were Frank T. Dierson, James F. Hoge and William E. MacKay, all of New York City. Newly elected to the Section's Executive Committee was James K. Robinson, Rochester.

George W. Sooy, Director of the Food and Drug Administration's Baltimore District since 1962, has been named as the agency's Regional Assistant Commissioner in Charlottesville, Virginia.

In the new assignment, Mr. Sooy will serve in the Region 3 Office of the Department of Health, Education, and Welfare. He is the second Regional Assistant Commissioner appointed by FDA. William V. McFarland was assigned to HEW's Region 7 Office in Dallas, Texas, last month.

Eventually, the FDA will have Assistant Commissioners in each of the Department's nine regional offices across the country. Their primary function will be to coordinate FDA activities with those of State food and drug officials and with other Federal agencies.

"GMP" as an Answer to Drug Recalls

By DOUGLAS C. HANSEN

Mr. Hansen Is Director of the Division of Program Operations with the Bureau of Regulatory Compliance, Food and Drug Administration.

IN SPITE OF EFFORTS BY THE DRUG INDUSTRY to produce safe and legal products, there are too many instances where unsafe drugs are finding their way to the marketplace. Time and again the same story is repeated. Complaints or injuries are reported in connection with a product which has a history of safe use. Investigation may show that only one lot, or possibly only a few packages, are involved. But something has gone wrong in the course of production or distribution which has destroyed the product's reliability and effectiveness. The defective drug is a health hazard and not a health aid. Obviously, those packages or lots must be taken off the market as soon as possible.

Both Government and industry recognize a recall as the most efficient manner in which hazardous products, already on the market, can be quickly and effectively removed. It is not a simple technique. The manufacturer must promptly contact each link in his chain of distribution. Communications must be faultless so there is no misunderstanding about which drugs are to be removed immediately from warehouses, taken from druggists' shelves, taken out of the hands of doctors, taken from hospital pharmacies and clinics. and, at times, even taken from the consumer's medicine chest.

These recalls are expensive. They can even be financially fatal to a firm. They are costly to industry and they are costly to the Government. Yet cost is not a factor to be considered in carrying out a recall. The only concern is what measures are necessary to assure safety for the users of the drug. It is the drug industry's responsibility to take all action necessary to remove the dangerous product from the market. It is the Food and Drug Administration's (FDA) obligation

to see that the corrective actions taken are adequate to protect the consumer. Only through proper coordination and cooperation between industry and Government can these responsibilities be met.

Upward Trend in Recalls

There has been a marked upward trend in the number of drug recalls in recent years. Prior to the Kefauver-Harris Amendments of 1962 the total number of drug recalls per year was less than 70. In fiscal year 1964 the number rose to 110; the following year there were 340 drug recalls, and during the past fiscal year, 449. As of the first of this month, the number is almost double the number for the corresponding period last year. This may raise the question, is the quality of our drug supply regressing? The answer is no.

Regulations issued following the Kefauver-Harris Amendments make it mandatory for industry to bring to our attention adverse reports concerning a number of drugs. With additional resources gained through increased appropriations, the FDA has been able to devote more manpower to seeking out defective drugs. The detection of penicillin cross-contamination in drugs, and, more recently, the detection of drugs contaminated with salmonella, are examples of the results of expanded FDA effort in the drug field. As a result of these two factors, FDA has been made aware of many instances of defective drugs which might not have been identified without the additional legislation and resources. Increased compliance pressure and industry's recognition that all unsafe drugs must be taken off the market would be expected to cause this upward trend to persist for several years in this post Kefauver-Harris Amendments period. However, we see no necessity for the trend to continue upward provided industry fully meets its responsibilities. What then is the answer to the problem? We say "GMP"—Good Manufacturing Practices—provide an answer to drug recalls.

Good Manufacturing Practices

The 1962 Drug Amendments contain a provision, Sec. 501(a)2(B), which states that a drug is 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 Practices to assure that such drug meets the requirements of this Act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

Following the enactment of these requirements, we convened a team of skilled operating inspectors, chemists and administrators from within FDA to draft guides for good manufacturing practices in drug factories. Proposed regulations were first published in February, 1963, and 45 days were allowed for comments. The final regulations were then redrafted to incorporate the desirable changes and became effective upon publication in the *Federal Register* on June 30, 1963.

The regulations are in general terms and set forth minimum requirements that drug firms should meet in order to achieve current good manufacturing practices. They serve as a basis upon which a manufacturer can develop the specific steps to be followed in his own plant to meet the requirements of the law.

Let us briefly review some of the principle points of the regulations:

1. Buildings shall be of suitable design, size and construction to provide for adequate manufacturing, laboratory and storage facilities. Segregated sterile areas for the aseptic filling of parenteral preparations should be provided.

2. Key personnel responsible for production and control operations should be appropriately qualified by education or experience and by a history of competent and reliable performance to insure the integrity of drug products.

3. Raw materials shall be properly stored and appropriately tested before use, containers clearly identified, and records maintained on each lot of raw material showing its origin, control and disposition.

4. A master formula record shall be properly maintained for each product. Batch records shall be properly prepared and maintained to show each phase of production, including check weighing and other controls necessary to avoid mistakes and errors. Each batch record shall be identified with a suitable identification number by which it should be possible to trace details of manufacture and control.

5. Processing equipment shall be cleaned between batches to prevent cross-contamination.

6. All in-process materials and equipment shall be identified as to product, batch number, date of manufacture, etc., to prevent mix-ups.

7. Special precautions essential in the manufacture of parenterals are required.

8. Quality control units must have adequate facilities, and must make necessary checks and tests to maintain the identity, strength, purity and quality of each lot of each product.

9. Strict controls shall be maintained for packaging and labeling. This shall include accounting for the labels issued and used, as well as disposition of reject units.

10. Adequate records covering distribution shall be maintained, by code number of products, to facilitate tracing lots in the event of injury or other circumstance necessitating recall.

11. Complaint files are required for all products.

12. Reserve samples of drugs should be maintained for two years after distribution has been completed.

These regulations represent the best thinking of Government and industry as to the necessary safeguards that drug manufacturers must observe if they are to continue to produce the safest and best drug supply found anywhere in the world. However, a review of reasons for past drug recalls clearly shows that over 75% could have been prevented by observation of the principles of GMP. Let me illustrate this observation with specific examples. It is clear that they would have been avoided if the manufacturers involved had adhered to these regulations.

Careless Manufacturing Practices

A physician reported to FDA two cases involving an increase in the size of the male mammary glands and one case of uterine bleeding. The three patients had been taking the same brand of APC tablets for a month. Examination of the tablets showed them to be contaminated with diethylstilbestrol (DES). Inspection of the manufacturer showed that canvas sleeves, or skirts, at the Fitzpatrick Mill in the granulating room had collected DES from a preceding run and undoubtedly had contaminated the APC powder.

A sample of 150 mg. tranquilizer tablets obtained during a routine inspection by a FDA inspector showed that one lot was 160% of declared potency. Investigation showed the problem was caused by improper label storage; that is, an employee had accidentally placed 150 mg. labels in the 250 mg. slot in the label rack. The wrong labels had been applied to the 250 mg. product; the error went undetected by the firm.

A drug firm purchased another firm's pentobarbital sodium injectable, a human drug, to be used during some animal studies. The injectable killed several dogs. Investigation showed the product had been mislabeled and was actually postassium chloride. Apparently, 50 unlabeled vials of potassium chloride became mixed with unlabeled

vials of pentobarbital sodium during an inventory check, resulting in this deadly episode.

Our analysis of drug recalls during the past fiscal year indicates that 351 of them, or 78%, were for reasons which could be traced to a failure to observe GMP. These reasons included problems of potency variation, cross-contamination with other potent drugs, non-sterility, label mix-ups and other misbrandings, decomposition, adulteration, such as contamination of opthalmic ointments with metal particles, and substandard qualities, such as the failure to meet all requirements of the official compendia. Obviously, there is a real need for more intensive attention to GMP by drug manufacturers.

Implementation of the Regulations

In implementing the "GMP" regulations, the FDA has followed procedures which we believe represent proper enforcement in this enlightened age. We first take steps to acquaint the regulated industry fully with the requirements of the law. We then try to assist industry in meeting these requirements voluntarily.

In cooperation with the University of Wisconsin School of Pharmacy and the Pharmaceutical Manufacturers Association, we have participated in seminars on control procedures and drug production, the most recent being at Hershey, Pennsylvania, this past July. We have participated in similar seminars sponsored by The Proprietary Association, the most recent being at Saddle Brook, New Jersey, just a month ago. Similarly, workshops will be presented by our field districts on a local basis to assist industry. "Good Manufacturing Practices" is the theme of each of these meetings.

From discussions during the seminars and from the history of recalls, it is apparent that GMP plays an important part in averting product errors and in detecting those that have occurred, thus preventing many potential recalls. For example, at the time the GMP regulations were issued, label mix-ups were the main reason for recalls. Industry tightened up labeling controls, and label mix-ups became an infrequent cause of recalls. Then came penicillin cross-contamination. Industry recognized the problem, observed the necessary GMP, and this became an infrequent cause of recalls. The pattern was repeated with respect to improper packaging of sterile surgical supplies and hospital aids. Now a major problem causing recalls appears to be Salmonella. Tightening controls over raw materials, a GMP factor, will reduce the problem.

Conclusion

This leads to the final part of my discussion. I mentioned that in implementing the GMP regulations we have taken steps to acquaint regulated industry with the requirements of the law. Also, we have tried to assist industry in meeting these requirements voluntarily. We are continuing these efforts. At the same time, both our investigations and the rising tide of recalls indicate that there are some firms which have not taken the necessary steps to bring their operations into accord with GMP. There comes a time when we must apply punitive measures if we are to do our duty and the public is to be protected. That time is now.

It is intolerable that so many defective products are still reaching the marketplace because of poor manufacturing practices. We are prepared to apply full compliance pressure against those firms who continue to violate the Current Good Manufacturing Practices Regulations.

[The End]

NEW PROCEDURE FOR COMMISSIONING OF STATE REGULATORY OFFICIALS

New policies and procedures for commissioning qualified State regulatory officials have been announced by the FDA. Officials will now be commissioned to perform one or all of the following specific functions pursuant to the Federal Food, Drug and Cosmetic Act: (1) conduct examinations, inspections, and investigations; (2) collect and obtain samples; and (3) copy and verify records. The commissions will be granted for a two-year period, renewable at the end of that time.

Last July, the FDA revoked all previously-issued State commissions and began a re-evaluation of the whole commissioning procedure. Although State officials had provided invaluable assistance in the enforcement of the Federal Food, Drug and Cosmetic Act, there were no procedures to assure that only State and local officials with sufficient training were carrying out investigations for the FDA.

The new procedures will require adequate information relating to qualifications, provide assurances that no conflict of interest exists, and give the FDA direct control over the issuance of all commissions.

Commissions are presently being offered to state officials responsible for administering State animal-feed programs. (Fourteen States—Oklahoma, Texas, Kansas, Utah, Wyoming, New Mexico, Colorado, Kentucky, Indiana, Michigan, New York, Maine, Massachusetts, and Maryland—are now participating in a joint Federal-State Medicated Feed Law Enforcement Program.) State and local officials engaged in other program activities similar to those of the FDA may be offered commissions at a later date.

The new commissioning procedures were announced in the *Federal Register* of February 15, 1967, 32 Federal Register 2903.

Assuring Drug Integrity — New Challenges, New Horizons

By L. PAUL SINOTTE, Ph.D.

Dr. Sinotte Is Director, Quality Control,
Merck Sharp & Dohme, West Point, Pa.

LAST WEEK I was taking a visitor through our manufacturing operation at West Point, Pennsylvania. And—as I find myself doing with almost all visitors these days—I took him over to see our new electronic tablet sorter. The operator was on his lunch break, so we were able to examine the machine without interfering with anyone's work. This apparatus electronically scans individual coated tablets, and is programmed to reject all tablets that are not in conformity with pre-set color standards.

It also scans for cracks, pits, or blemishes of any kind on the tablets. We reached into the reject cup to see just why some of the tablets were electronically cast into that category. Most of this group of tablets—a very small percentage of the lot by the way—were there because of some slightly off-color smudges on their surface. No cracks or pits in the reject cup. And certainly no foreign tablets. Just a few smudges.

This machine makes me reflect each time I see it on how far we've come in this business of pharmaceutical manufacturing and quality control. It makes me think, too, of Emma Dilks. I'm sure you don't know Emma Dilks. But Emma Dilks became well known around Merck Sharp & Dohme about a year ago for picking a foreign tablet off a conveyor belt. The foreign tablet was the same color coating and curvature as its companions on the conveyor. The only difference was a slight change in dimension. But she spotted it.

And we gave Emma an award for spotting it. Emma is, of course, a tablet sorter, and she can reasonably be expected to spot things like foreign tablets of different color and shape, even though we don't expect such tablets to be there for Emma to spot. Her job really is to sort out the cracks and dents and other things. The reason

we made a big thing out of her finding the foreign tablet of the same color are: First, this is the sort of thing we never want to reach the drug store, let alone the patient. (There are other points at which it may have been found, but we are glad it didn't get by Emma. In this particular case, we discarded the entire lot just to be doubly certain there were no additional foreign tablets.) Second, this is the sort of thing that might have occasioned an expensive search and recall, if it got too far along the path of distribution. Third, we recognize the difficulty of sustained concentration that is needed for a job like Emma's, and we wanted to do something to re-emphasize the importance of the work she and her fellow tablet sorters do.

But, to get back to the electronic sorting machine. It is presently capable of handling coated tablets up to 3,000 a minute, and we're working to adapt it to more of our products. I think it is safe to say that the use of this type of equipment can and will be expanded.

I am going to be mentioning other measures, other machines, that are making "Quality Assurance" even more precise, refined, and significant today, and that will be making it more significant in the future. But I wanted to bring in Emma Dilks, right in the beginning, for two reasons: First, just because new and better methods are coming along, I wouldn't want it assumed that all previous methods were substandard or inadequate. All the Emma Dilkses of the world have done, and are doing, a marvelously conscientious job. When you consider the *billions* of tablets that have passed under their collective eyes in recent decades, one can't help being impressed by the tiny percentage of error that has occurred in this area. The second reason is even more vital: Let Emma Dilks remind us all that no matter what machines we install, and regardless of their capability, the human factor will always be present in this business of assuring quality. We intend to design all operations to be as foolproof as possible. But, no matter how far you squeeze down the percentage, there will always be a human element present. I think everybody must recognize this, and I think everybody must build this recognition into their systems.

Dynamic Imperatives of Quality Control

But, before listing some of the technological improvements, I want to clear up what I mean by my title, "New Challenges, New Horizons." These two ideas merge and overlap, to my way of thinking, and they rest on what I call the "dynamic imperatives" of quality control. Call them basic assumptions, if you will. There are six of them, and they serve as a background to everything we do.

(1) There are, and will be, an increasing number of pharmaceutical products. Never mind if some of them are merely differences in combination or dosage strength. In production, packaging and quality control, these differences are just as important as any other. At Merck Sharp & Dohme, we currently have around 360 different products, not counting the variations created by different size packages, which is further compounded by special labeling for international distribution.

(2) Many of these products will be more complex than their predecessors, from a quality control point of view. And, even when they are not more complex, the mere fact that they are *different* means we must establish a quality control approach tailored to match each specific product. As many of you know, the removal from availability of many colors, which serve for product identification purposes, makes the job even more challenging.

(3) There will probably be an increase in the number of pharmaceutical products that have even more potent effects on the human body. These products, as we all know, have considerable potential for harm if misused or made improperly, just as they have vast potential for benefit when made and used properly.

(4) Our ability to detect imperfections of all kinds, since it is based on the state of technology, is bound to advance. In the future we may be able to find some types of deviations, however slight, that are presently undetectable, right down to the billionth part. (This, by the way, creates problems that are not as simple and obvious as they appear on the surface. After all, how far *should* we go in this direction? How far is far enough? An engineer designing a bridge, for instance, designs his product for maximum contemplated stresses, and then adds a safety factor. He doesn't build his bridge to withstand 100 or 1,000 times its contemplated maximum load simply because he has the technology to do it. To do so would be unnecessarily wasteful of resources that could be more usefully applied elsewhere. It would be economically and, if you will, socially undesirable. In pharmaceutical quality control, we may be approaching it in some areas—and I stress *in some areas*. And you can't really say a bridge is entirely different from a pharmaceutical tablet, because safety is very much involved with both.)

(5) My fifth "dynamic imperative" is really part of the fourth. It is this: our advancing technological ability to detect deviations will be matched roughly by our advancing technological ability to analyze our mistakes and correct them.

(6) The sixth "imperative" is the everlasting, never-ending *determination to excel.* This is the human component I talked about earlier. It belongs on every list that deals with a human concern or enterprise. Leaving it off is like drilling a hole in the bottom of the bucket.

This then is the framework of present and future realities as we see them, very briefly and incompletely stated, I hasten to add. These are the challenges and the horizons of industry's quality control effort, as we see it at Merck Sharp & Dohme.

Specific Control Programs

I would like to turn now to some of the specific programs we have in progress. The items I will mention, of course, are examples of quality control programs at Merck Sharp & Dohme. While I am proud of the work we're doing at MSD, I would like to say at the outset that I know my colleagues in other firms in the pharmaceutical industry are making significant efforts in this area as well.

What are some of the things that are being done with advances in technology?

I have already mentioned the electronic scanning equipment for tablets. This, I believe, is a "first" for Merck in the industry, but I would predict it will come into general use by quality-conscious manufacturers, just as the automated system for individual tablet assays has come a long way in the past four years.

This automated tablet assay system, as most of you know, is a device that grinds, dissolves, mixes, analyzes and records assays on individual tablets at the rate of 20 to 40 an hour. According to our calculations, it would take a trained chemist one whole working day, or eight hours, to perform assays on about one dozen tablets. So the rate of improvement is in the area of 15 to 30 times greater.

This device, part of which was invented in our quality control laboratories, is now in widespread use. As you are aware, it has meant vast improvement in two directions. First, it permits us to do a higher level of sampling than previously. And, second, it makes the technique of individual tablet assays possible with more products. Previously many assays, as a practical matter, had to be performed by grinding tablets together and computing averages. Partly because of this apparatus, you'll be interested to learn, there were 14 products listed in the new USP and NF calling for *individual* tablet assays. And I know there will be more as time goes on.

Then, there is the matter of dust particle control. We know, from careful studies, and because of the sensitivity of the testing procedures, that our cross-contamination is way below a few parts per million. Nevertheless, at our Company, we have just completed an expenditure of over half a million dollars to further cut the possibility of contamination. Our granulation and tablet-compressing is being performed in separate cubicles that may be completely washed down with every change of product. The air flow and uptake is arranged to keep particles from floating out of the cubicles. In compressing, each cubicle has its own in-process testing equipment, thereby minimizing confusion as well as possible tablet mix-up.

At the same stage in time, our chemists will develop tests to detect even lower levels of contamination. The dust control program is designed to minimize the occurrence of cross-contamination at these lower levels. Somewhere along the line it may become reasonable to ask: When does contamination cease to be contamination?

Engineering Contributions

Today, the quality control effort is not limited to the laboratory scientists and technicians. The engineering approach is also included, as we strive to impose consideration of quality on every step in the manufacturing and packaging process. The dust control program is an example of this combined approach. Another example would be the special separation and semi-partitioning of all our packaging lines.

Further examples would include recent moves to make our packaging operation foolproof. We print labels in rolls rather than sheets, reducing the possibility that an incorrect label might be used in packaging a product. And, in addition to the label checks that are made by personnel in the packaging area, we have adopted electronic scanning devices that will identify the labeling used on every individual carton, every shipping and every packaging container. These devices are set to allow only one code to pass by. The labels might be similar in general appearance to the human eye, but not to the scanner which "sees" only the special code.

And what about quality control on potency? This may be largely a question of product stability. It is a many-sided quality problem, and, unfortunately, there are no short-cuts to success. In addition to all the stability work done in research, under a number of temperature and humidity conditions, where the quality is built into the product, we in production have a procedure, for the addition of each new product to the line, which calls for taking samples right off the production line and storing them under simulated pharmacy condi-

tions. Then we test them on the average of every three to six months for five years, looking for drops in potency or changes in pharmaceutical elegance. We also test material exposed to actual storage conditions in different geographical locations. None of these efforts is static. We are constantly seeking ways to improve them.

The Human Element

And, what about the human element I mentioned earlier—the element we shall never be able to forget no matter what technological progress should occur? The "Good Manufacturing Practices" are important here, as you all know: adequacy of procedures and equipment, adequacy of instructions and training, general morale.

But over and above all that, there is something else. It's somewhat elusive, but it can be defined, isolated to some extent, and improved. I'm talking about motivation, quality motivation. At Merck Sharp & Dohme, we try to stimulate this through our Pride in Quality Program (P-Q), which is our refinement of the Zero Defects Concept. We say "a refinement," since it is aimed at the *fractional* percentage of improvement remaining in our industry to achieve 100 per cent quality assurance. The prime objective is to instill purposeful quality commitment in every single employee of the company. It was under this program that Emma Dilks got her award for finding the foreign tablet. Around 50 others have received awards for outstanding achievements or continuous quality performance in the past year. Over 300 people have turned in usable suggestions for the improvement of our performance in all areas. These suggestions can be for the refinement of procedures or for new procedures to avoid repetition of past faults. But more often they are for the changing of a situation which, in the mind of the person submitting it, *might lead* to an error if the situation isn't changed. This adds a new dimension to the idea of suggestions, and it has resulted in a number of quality actions taken which might have been overlooked or delayed without the wholehearted participation of all our employees in this way.

Conclusion

In summary, we in pharmaceutical Quality Control are operating in an environment permeated by what I have called "dynamic imperatives," which make progress along many fronts both desirable and inevitable. There are some gaps and lags, because these "imperatives" do not always advance on an equal front. But the whole thrust is clearly moving *toward* the goal desired by everyone—greater and greater assurance of product quality by *meeting* the new challenges, *seeking* the new horizons. **[The End]**

Introductory Statement

By FRANKLIN M. DEPEW

The Following Introductory Statement Was Given at the Twenty-Second Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association. Mr. Depew, President of the Food and Drug Law Institute, Was Chairman of the Meeting. Succeeding Papers in This Issue Were Presented at the Same Meeting.

I AM HAPPY TO WELCOME ALL OF YOU to the Twenty-second Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association and am glad to note such a fine attendance. This is in keeping with our membership, which has increased, according to the last tally at Bar Headquarters, to a total of 732. This reflects an ever increasing interest in the problems of food, drug and cosmetic law.

Our program today consists of ten interesting and valuable papers. I am confident you will find them most useful and beneficial. I take this occasion in your behalf to thank all of the speakers for coming here today to address us on these important matters.

Since last we met there have been two developments of considerable interest to all—the passage of the Fair Packaging and Labeling Act and the proposal to revise the Special Dietary Regulations. These have given and will give everyone in and out of government numerous new and challenging problems. I hope that what is said here today will at least help you cope with these problems, if not to solve them.

Dr. James L. Goddard has now been our Commissioner of Food and Drugs for a little over a year. During that period he has been burdened with heavy responsibilities. However, he seems to have a resiliency which has enabled him to keep things moving and to get things done. I am sure we are all honored and pleased that he is here with us today to report on progress in the Food and Drug Administration and to tell us how we may be able to help him in carrying out his responsibilities. [The End]

The Year in Review

By JAMES L. GODDARD, M.D.

Dr. Goddard Is Commissioner of Food and Drugs

I AM DELIGHTED TO SHARE WITH YOU some impressions I have gained from a year as Commissioner of Food and Drugs. You may or may not remember, but on the 17th of January I noted the passing of one year with the Food and Drug Administration (FDA). More accurately, I should say that my staff marked the anniversary with a special coffee-break. Without that reminder, the date would have probably passed me by unnoticed. My calendar groans under countless notations that, I am afraid, take precedence over birthdays and anniversaries.

But as you can tell, I was glad to have been reminded by the staff of my office that a year had passed. As a footnote, I might add that a home-made cake was brought in and we were all assured that it was "absolutely Salmonella-free." And it was.

The Salmonella-free cake was a nice touch. It symbolized a number of things that also could have been present at our little anniversary coffee-break: peanut-butter hors d'oeuvres, vitamin-and-mineral pills to give me the pinch of magnesium or phosphorous that was probably missing in the cake, long-acting aspirin tablets to help me get through the rest of the day, now that the shock of the anniversary had penetrated. Instead the staff thoughtfully limited the symbology of my first year to a Salmonella-free cake.

I haven't said much in public about 1966. With your permission, I would like, therefore, to take this opportunity to ruminate about that year and to let you know some of the things I think we did that were important and some of the things we learned as we did them.

We often tend to speak rather casually of foods, drugs, cosmetics, and hazardous substances, leaving the impression that we lump these together in our day-to-day administration. But these are quite different industries, intensely competitive, highly innovative, and in direct contact with every American consumer.

Individual pharmaceutical manufacturers have chided me for speaking about such a thing as "the drug industry" at all. There is still enough individualism in drug manufacturing so that the phrase "drug industry" is received grudgingly—at best—even by long-standing members of the Pharmaceutical Manufacturers Association.

The so-called "food industry" is really a panoply of industries. Yesterday I had the pleasure of speaking before the "canning industry." A few weeks ago I met with the "frozen food industry." There is the "baking industry," the "fish industry," and many others. The products they make may well fit neatly into nice, square boxes—but the manufacturers do not.

I have discovered that the FDA and the cosmetics industry have been engaged in a game of hide-and-seek, as well as actual litigation, for so long that when speaking to its representatives, I am almost reduced to addressing them as "you people." I am sure the cosmetics industry is there and it may be that the hallmark of my second year in office will be to have found it. Joking aside, we are already having good discussions with leaders of this industry.

Of course, there is no "hazardous substances industry" as such, but we do have a vital interest in such substances that come from a variety of industries. This interest was strengthened by Congressional passage last fall of the Child Protection Act, which President Johnson proposed as an amendment to the Hazardous Substances Act.

In a word, then, I discovered quite early that the FDA cannot do business with business if the agency remains enchanted with its own generalizations *about* business. Nor can we go too far in generalizing about one group of manufacturers on the basis of experience with another group—whether they are members of the same so-called industry or not.

FDA Reorganization

As a result of this kind of thinking and evaluating, we have taken a second look at the way the FDA is organized and we have gone through a reorganization. Nominally, we are just about over the main shifts of functions and programs. However, the FDA will never be settled into a static framework. Not because of anything I or any other Commissioner might do, but because of what the regulated industries are and the way they are accelerating their own rates of change. Either the FDA keeps abreast of them and regulates them in accordance with their dynamics as well as in accordance with consumer needs—or we go to our President and to the Congress, explain our dilemma, and ask for help.

Looking back over 1966, then, I must say that the reorganization of the FDA—not only in terms of little boxes on charts but in thinking and planning as well—has been a major undertaking with broad implications. We are now in the process of examining our field operation in depth, to see how we might make it function better in the contemporary marketplace. Thus far, I have spent at least one day in most of our District Offices. And next week I will have the pleasure of meeting with our 18 District Directors in Washington for a further exploration of improving our field management.

Secretary John W. Gardner once wrote, "Perhaps what every corporation (and every other organization) needs is a department of continuous renewal that would view the whole organization as a system in need of continuing innovation." Our FDA staff is putting that concept of "continuous renewal" into effect, and I believe it is part of the excitement of working in our agency at this time.

A second major effort has been to comb back through the Kefauver-Harris Amendments in order to see how well—or how poorly—the FDA is carrying out the law. We found that a number of areas needed further attention. We also found that such attention had administrative ramifications that had to be analyzed and resolved.

And let me say right here that the oversight function of the Congress is essential to an agency that really wants to buckle down and do a job. It is very easy for an administrator to become so immersed in day-to-day headaches that he loses perspective on his whole program. His subordinates very often follow his non-lead.

One or two days occasionally as a witness on Capitol Hill prove to be salutary, I have found. Last year I had the privilege of appearing first before Representative L. H. Fountain, Chairman of the House Subcommittee on Intergovernmental Operations. This year began with our appearance before Senator Harrison A. Williams, Jr., Chairman of the Senate Subcommittee on Consumer Interests of the Elderly. In these as in other instances, our entire staff must do that extra bit of homework that keeps them—and me, as well—alert to our total agency program, as well as to its specific bits and pieces.

Thus, we have gone back through our legislative mandates—particularly the Kefauver-Harris Amendments—to take stock. You will note that we have taken a firm position on the drug advertising provisions, that we have begun to implement the official name provisions, that we have pursued the role of the clinical investigator under the law, and have made some decisions on that matter as well, and that we have taken several broad actions in the area of efficacy.

A number of drug manufacturers—and a few members of the medical profession, too—have expressed concern about these activities. Frankly, *I* am far more concerned about the FDA *not* doing the job it has been assigned. In this connection, I am reminded of a sentence in President Johnson's State of the Union address. The President spoke in terms of the entire Nation, but I would like to apply the thought to the FDA. President Johnson said, "And now we must answer whether our gains shall be the foundations of further progress, or whether they shall be only monuments to what might have been—abandoned now by a people who lacked the will to see their great work through."

We have tried to carry out with increased vigor our agency's mission. We have embarked upon new trails. And we will not be deterred from such a course, merely because it may bring some discomfort to a well-protected few. Our main job is the protection of the many. We have no plans to abandon it.

Consumer Protection

In addition to regrouping and renewing the Food and Drug Administration, and in addition to expanding our efforts in carrying out the law, I think we have also been giving deeper thought to the phrase "consumer protection." In the past, the protection of the American consumer was usually centered around what protected his pocketbook, with many other areas of concern coming in almost tangentially. This is an overstatement of the case, to be sure; but today the concept of "consumer protection" is really much broader than it was, say, a decade ago.

Today we recognize that Americans must be protected from a variety of challenges in our environment. Some of these challenges are still economic frauds and cheats, to be sure, and we must be vigilant against them. But consider these others:

Microbiological contamination of foods
Impure or subpotent drugs and drugs that can be abused
Unsafe chemical and biological residues in food
Water-borne chemical pollutants
Air pollution
Excessive environmental noise
New kinds of occupational stress

The Food and Drug Administration is concerned with only a few of these challenges to man. However, it is not possible to deal with

them as if each one were isolated or compartmentalized. Let me give you one example involving a major new program begun in 1966.

Last February 1, 1966, we put into effect the Drug Abuse Control Amendments of 1965. The traffic in certain drugs—barbiturates, amphetamines, hallucinogens, and a number of combinations—has come under FDA control. And we are naturally pursuing, with the aid of the National Institute of Mental Health (NIMH), this phenomenon of drug abuse: what it is, who is involved, how extensive it is. Some early conclusions are already in. As Mr. John Finlator, the Director of our Bureau of Drug Abuse Control, has reported, this is "a middle-class phenomenon." We are not dealing with furtive addicts hiding in bare rooms or unlit hallways. We are in suburbia; we are in so-called "weight-watching clinics" frequented by housewives and mothers; we are among highly motivated young executives; we are among students and new careerists. Our investigators start with the "nice people" who have formed the drug habit and then they work back to the pusher and the illicit manufacturer.

The suburban housewife who has become habituated to amphetamines is in need of our protection. We may cut off her illicit supply, but what have we done to protect her from the need for the drug? She is still challenged by noise—radio, television, the telephone, jets, street traffic, and people living very close by. She breathes air that has had a liberal chemical contribution from buses, cars, and planes. Her drinking water comes from the faucet with traces of nonsoluble detergents still in it. She is aware of the fact that virtually all her food has been treated with chemicals in some way and that she has no control over that chemical intake for herself or her family. She is not living in an idyllic environment; if she dwells upon that realization and if she sees no real protection from these challenges, she is very likely going to seek her own kind of "protection" through the abuse of certain drugs.

This is just for purposes of illustration. I certainly do not wish to pre-empt the position of Dr. Cole or Dr. Yolles of NIMH or of our own Dr. Fox putting together a profile of a drug abuser. But I do want to make the point that protection of the American consumer, as we now recognize it, is not subject to simplistic answers or simplistic programs. The very environment of the consumer is a web of contrary influences, a web through which we have only progressed a very short way and in which we are constantly on the verge of becoming lost.

So in this last matter of consumer protection, I would conclude by saying that we are continuing our campaign against quackery and all

the economic and health frauds. Also, we are soon to embark upon the implementation of the Fair Packaging and Labeling Act, to protect the consumer from deceptive practices in the marketplace. Our General Counsel, Mr. Goodrich, will speak of that. But beyond that we are pursuing the significance of food additives, pesticides, cosmetics, drugs, and other substances as they press in together upon contemporary man.

It is all very well to recount to you some of these major issues that have appeared to me during the past year: reorganization, broadened regulatory activity, and a more encompassing view of consumer protection. But the question arises, "How best can each individual problem be worked out?"

Participation by "Third Parties"

The FDA is, of course, a regulatory agency first and foremost. Hence, as each new day brings its batch of problems to my desk, I find that we are in a nearly constant state of confrontation: we confront one or another drug company; we confront a segment of the food industry; we confront an industry association or a professional association. At first, I thought this would have to be the order of things in the agency. But I soon learned that it need not always be the case. There *are* times when no one's interest—neither the public's nor the industry's—is served by having the Food and Drug Administration on one side of a table and an adversary on the other side. The result can be a stand-off—and progress is not measured in stand-offs, I would venture to say.

There are times, therefore, when third parties are necessary to the making of progress. I would like to cite some examples of how the FDA has turned to different kinds of third parties for assistance. We have done so not to abdicate in any way our own responsibilities, but in order to better fulfill them.

FIRST, I think one of the most important decisions of this kind was the seeking of the aid of the National Academy of Sciences—National Research Council in our drug efficacy review. It was clear that the FDA had to get an efficacy review accomplished involving all 1938—1962 drugs. But it was equally clear that we did not have the staff to do it. In addition, it was clear that we would be confronting drug manufacturers at every turn with contrary interpretations of data. A third party was essential. And I am very pleased that the Academy agreed to be that third party.

SECOND, there has been a great deal of activity by our agency in the field of prescription drug advertising. We have made some seizures and we have other cases in the pipeline. I cannot recount to you the number of hours many of my staff and I have spent with individual drug company executives on the matter of violative advertising. But here, again, we have found that merely confronting the offending company was not enough. We had to turn to a third group that had the ability to move between the FDA and the drug sponsors with some degree of freedom, as well as with interest. From this conclusion came our decision to take the FDA point of view directly to the advertising profession. Last summer and fall, our staff opened up new channels of communication with the advertising agencies and I think that some progress has been made as a result. For no matter how much the FDA amplifies its position and no matter how much the drug companies disagree, it is the advertising man himself who, ultimately, must collect the thoughts of both sides and produce the final ad. We are continuing this exchange with the advertising profession and I think it will continue to be fruitful.

THIRD, I would want to emphasize that the Food and Drug Administration does not wish to regulate the practice of medicine. Rather, we see our task as making available to the medical practitioner those therapeutic agents upon which he can rely. This is a point to keep in mind when one considers the so-called "children's aspirin conference" which we convened in November. That conference was suggested by the Congress and it was a good suggestion and another example of the value of legislative oversight. We brought together the makers of children's aspirin and ourselves. But the success of the conference—and it *has* been regarded as a success by everyone—revolved around the presence of a number of distinguished practitioners of pediatric medicine. They were neither *pro* nor *anti* anybody; they spent the day with industry and the FDA to get specific jobs done: agree on a standard tablet and agree on a tablet limitation per retail container. Both of these were defined, and there was other good discussion, too. Clearly the presence and active participation of this third group of doctors made the conference a good one for both industry and the public.

You may recall that I began my remarks today with some comments about the diversity of the industries we regulate—diversity to the extent that it is quite difficult to lump any three companies together on almost any basis. It is equally difficult, therefore, to assume that industry associations—and we deal with nearly 200 of them in one way or another—can always provide the necessary middle ground at a

time of pending conflict. This may be a disappointment for some executive secretaries to hear, but I'm afraid that it is a reality for us.

It has been—and I believe will continue to be—our feeling at the Food and Drug Administration that the seeking out of guidance or assistance at critical times from third parties is useful and serves the public well. We turn to the university community. We work with independent management consultants. We are open to a variety of third parties, if they can help us accomplish our tasks more effectively and efficiently without compromising our special responsibilities in each matter.

This, then, is a brief review of some of the things that linger in my mind as having significance during the past year, my first as Commissioner of Food and Drugs. It has been a very satisfying year, I might add. I enjoy the work, I value the many new friends I have made in the agency. And I am looking forward to the further development of the Food and Drug Administration as a strong and vital member of the national health effort. **[The End]**

FOOD AND DRUG LAW INSTITUTE PREPARES SECOND ANNUAL ONE-DAY SEMINAR

The Food and Drug Law Institute, Inc. will present a Second Annual One-Day Seminar on "Legal Guidelines for Self Regulation in Advertising, Labeling and Promotion of Drugs" at the School of Law, Northwestern University in Chicago on Friday, April 14.

The Seminar will provide an opportunity for members of the legal, medical, advertising and promotional staffs of pharmaceutical manufacturing concerns and their advertising agencies to update their own information in this important area. A panel of experts will address the Seminar. Dr. Robert S. McCleery and Harold W. Chadduck, Acting Director and Deputy Director, respectively, of the Division of Medical Advertising, Office of Medical Review, Bureau of Medicine, FDA, will be present. Mr. Julius Hauser, assistant for regulations in the office of the Associate Commissioner for Compliance, will speak on the subject of FDA goals in the labeling and advertising regulations. David Sutton, Vice President for Marketing, Arnar Stone Laboratories, Warren Whyte, Esq., Senior Attorney for Regulatory Law at Abbott Laboratories, and Arthur Wright, Esq., Attorney, Baxter Laboratories, will represent industry. Serving as principal lecturer in presenting the fundamental legal materials that apply to the entire area will be Sidney H. Willig, of the FDLI's Lawyers Advisory Committee and Instructional Staff. Pre-registration is recommended, and it is suggested that reservations be made prior to April 1st. The fee is $25 per person which includes luncheon. For further information, address inquiries to Franklin M. Depew, President, Food and Drug Law Institute, Inc., 205 E. 42nd St., New York, New York.

Reflections on Food Standards

By VINCENT A. KLEINFELD

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IN MY PAPER, THERE ARE CRITICISMS—some I hope are constructive—of food standards and food standard procedures. I believe that new and different, perhaps daring and controversial, thinking is needed to make standards dynamic so that they can really benefit both the consumer and industry.

I would hope that some strides would be taken comparable in scope to the highly constructive step taken recently in the drug area. I am referring to the arrangement under which pre-1962 new drugs have been referred by the Food and Drug Administration (FDA) to committees established by the National Academy of Sciences-National Research Council. By that thoughtful and creative action, the consumer, the FDA, the small drug manufacturer and the large drug manufacturer will be benefitted. This is because pre-1962 new drugs (approved as to safety by the FDA and on the market for years under the Agency's surveillance) which gain the approval of the committees, composed of some of the greatest experts in the fields of science and medicine involved, will of course no longer be new drugs. The public will be greatly aided because it will receive, as it is entitled to receive, drugs which have been found to be safe and effective. The FDA will be helped because it will not have to expend its valuable time uselessly in examining new drug and supplemental new drug applications for those pre-1962 new drugs which are cleared. The small drug manufacturer (as long as he observes good manufacturing practice) will be in a position to market these drugs without submitting costly and time-consuming new drug applications. And the large drug manufacturer will not have to submit unnecessary supplemental new drug applications in connection with changes in manufacturing facilities and the like. This is the general kind of forward-looking thinking and improvisation I have in mind for the food standards area.

At this stage of our civilization, there is a genuine need for the use of literally hundreds of non-basic ingredients in our food supply. Few would quarrel now with the advisability of enriching various foods with vitamins and minerals or with the addition of other substances which enhance the nutritive value, shelf-life or eye-appeal of the products in which they are incorporated.

It seems to me that we can feel proud of the tremendous research and progress in the field of food technology. This has resulted in an improvement in the health and nutritional status of millions. Nevertheless, in the complex civilization in which we now live, the ordinary consumer frequently is in no position to judge the quality of the foods she is purchasing. Legitimate industry is helped and not hampered by reasonable legislation and reasonable administration which offer to the public the economic protection to which it is entitled.

Establishing Reasonable Standards

The five years of legislative history of the Federal Food, Drug and Cosmetic Act reveal that one of the important problems with which Congress was concerned was the establishment of definitions and standards of identity for foods. The sale of inferior products which, the hearings disclosed, created confusion in and deception of the consumer was believed by Congress to be a real economic evil. The marketing of jams such as "Bred Spread," containing considerable water rather than fruit, presented a typical example and was discussed widely at the Congressional hearings.

The result was section 401 of the 1938 Act, providing for the promulgation of regulations establishing definitions and standards of identity for foods whenever, in the judgment of the Secretary, such action would promote honesty and fair dealing in the interest of the consumer. The criterion established by Congress with respect to the standards was that they be "reasonable."

In my opinion, there was a definite need for section 401. The section should have been a boon for the consumer, as well as for responsible food manufacturers and processors. Unfortunately, it has fallen short of this expectation.

As I see the situation, the reason for the fact that definitions and standards of identity are not held in high esteem is that the government has not consistently and in a timely fashion pursued the fundamental objective of the section; to wit, the establishment of food standards which are "reasonable." A most important facet of being reasonable, of avoiding inordinate delays and over-lengthy hearings,

is not to concern oneself with peanuts, but rather with the important, the basic, facts of life in the field of food standardization. And as Dr. Goddard stated in his memorandum to the personnel of the FDA in connection with the Sixtieth Anniversary of the passage of the Food and Drugs Act in 1906, "law is only a tool," and its effectiveness depends in part on "the good judgment" of those "who are charged with the responsibility for its administration."

Prior to the passage of the Food Additives Amendment in 1958, there was a reasonable basis, both in law and in fact, for the position that no optional ingredient should be permitted in a standardized food unless its safety was established to the satisfaction of the government. This, of course, led to time-consuming, expensive and unseemly feuds between competing manufacturers at food standards hearings. Nevertheless, it was important that the FDA be satisfied that no hazard was presented by any ingredient utilized in standardized food.

It would seem, however, that a reasonable position, immediately after the passage of the Food Additives Amendment, should have been that if one optional ingredient serving a specified functional purpose was to be permitted, any other ingredient serving the same purpose should be permitted if it was generally recognized as safe or was an approved food additive. The "breaded shrimp" philosophy should have been pursued many years before the government grudgingly took the step it did take in that standard. There was no reasonable basis for not going that far.

But if, at long last, standards are going to be reasonable, why should not the government go further? If the major ingredients of a food which is being standardized are established, together with their levels of use, and we overcome the traditional reluctance to change a position taken for many years, it would appear to be patently reasonable to permit the use of any optional ingredient which (1) is generally recognized as safe or is an approved food additive and (2) does not create deception, or economic adulteration or sophistication.

The Need for Communication

I believe, also, that in seeking initially to determine what is a "reasonable" definition and standard of identity for a food, we should go back a few years to the days when it was not deemed to be evil to confer at length with industry before the issuance of a proposal to standardize the food. Certainly such informal discussions do not necessitate, by any means, that the Food and Drug Administration adopt in whole or in part any position urged by industry. But nothing

is lost by such discussions, and a friendly and informal exchange of views could be most helpful to all concerned in the standard-making process. This appears to be in line with what Dr. Goddard has in mind. Last June, in his speech at the meeting of the Grocery Manufacturers of America at White Sulphur Springs, the Commissioner stated in part:

". . . our agency will be moving forward to establish new standards of identity for a number of food categories . . . . The food industry should be able to anticipate our actions in this endeavor and come to us with some constructive suggestions. Naturally, the final decisions will be ours, but that does not preclude communications between us beforehand. As I indicated earlier, full and open communications between industry and our agency is a basic tenet in my administration."

It is well to advert to the tendency of some government officials to take the view (although this is not publicly stated) that it really does not make much sense to have hearings at all in most instances. After all, once the FDA has reached a position, it must, by definition, be reasonable and, therefore, what is the point in wasting time and money by holding a hearing, particularly since rule-making proceedings are often costly and time-consuming? A modicum of self-restraint on the part of these officials would be most helpful, as would be the belief that even the Food and Drug Administration may conceivably be wrong in some isolated and remote instance. A little modesty would be most becoming.

Rule-Making as Quasi-Judicial Procedure

In any event, this growing reluctance to hold hearings is not supported by legislative history. The original pertinent provisions of the Federal Food, Drug and Cosmetic Act, enacted in 1938, required a hearing upon any proposal initiated by the Secretary to issue or alter any substantive regulation, even where there was no dispute. Congress chose to adopt an unusual approach by imposing on the rule-making powers of the Secretary the safeguards customarily applied in quasi-judicial proceedings.

The Federal Food, Drug and Cosmetic Act embodied the growing tendency on the part of Congress in the latter half of the New Deal era to impose strict procedural requirements upon regulatory agencies in the exercise of rule-making powers. Under the Act, the Secretary was required to observe a careful procedure in promulgating regulations. The basic requirements of quasi-judicial proceedings were incorporated into the rule-making processes under the Act.

The Congressional purpose was obvious. Because orders are ordinarily proposed by the FDA, and because such proposed orders generally have an important impact upon industry as well as the consumer, Congress created a specific mechanism to test, by public hearing, and by the invaluable processes of examination and cross-examination, whether the order should be promulgated. In fact, Congress felt so strongly about the necessity for preventing arbitrary action and providing for a record based upon the traditional judicial and quasi-judicial concepts of examination and cross-examination, that it required a public hearing even where there was no objection by industry to a proposed order of the Secretary.

Experience under the Act subsequent to 1938 demonstrated that it was unnecessarily burdensome, time-consuming and expensive to require a hearing in every instance, since many proposals were outside the zone of contention and were satisfactory to both the Secretary and industry. Accordingly, at the specific suggestion of industry and with the support of the Food and Drug Administration, the Act was amended to require a hearing only for those proposed regulations to which persons adversely affected specifically objected. This was the specific reason for the amendment.

The legislative history of the original Act revealed in most clear and unambiguous language that Congress meant what it said in explicitly requiring a hearing in connection with a proposal of the Secretary to issue, amend or repeal a regulation. The legislative history of the amendment to the hearing provisions is equally specific in pointing out that the right to a hearing was to be preserved where a controversy existed, and that the amendment was sought only in order to omit the need for a hearing on any proposal, or portion of a proposal, by the Secretary to which no objection was taken. For example, the pertinent House Committee report stated that the proposed legislation was favored by both government and industry "because it should provide the needed relief from these unnecessary burdens by eliminating the requirement for formal hearings except in instances where such a hearing is desired for the purpose of providing a basis for the judicial review as now provided in the Act, should the objecting party find the ultimate regulation still objectionable." Yet the amendment to the Act, clearly designed to expedite hearings and remove the necessity for them only where there was no objection concerning the reasonableness of the contemplated regulation, has been converted by the government into an authorization to the Secretary to grant or refuse a

public hearing in his discretion on the basis of whether the objections advanced could possibly change his mind.

Fairness in Hearings

In a speech made by the Chairman of the Federal Trade Commission (FTC) a few months ago he said, and I quote: "Fairness having been assured [by the Administrative Procedure Act], the inquiry has become: How well is each administrative agency performing" its task? But has fairness been assured? Let me talk for a few minutes about the administrative hearings held by the FDA. There are two types: rule-making and adjudicatory. The former type, applicable under section 401, is supposedly impartial. Notice is given, a hearing is held, an opportunity is given for the examination and cross-examination of witnesses, there are findings of fact, an order is made, and judicial review is available. As I have indicated, the legislative history reveals the specific intent of Congress that the pattern of quasi-judicial proceedings be pursued.

Has this pattern been followed? For example, does it constitute fair play, at the conclusion of a hearing, to have the governmental officials who testified, and who were diligent, forceful and zealous proponents of the government's position throughout the hearing, review the record and make comments and recommendations to the Commissioner? After all, even those who are employed by the government are human beings, with both the virtues and frailties of other human beings. It is unfortunately true, also, that in many instances in these rule-making proceedings the order upon which the hearing is based is one which the government has definitely made up its mind to issue. It is obvious at the hearing that this is so, and the hearing is factually, if not theoretically, an adversary proceeding. The FDA has one of its attorneys present who acts as an earnest advocate, strongly attempting to sustain the order. For many years, the examiner before whom he pleaded was another attorney in his office. Both were members of the General Counsel's office performing counseling functions for the FDA. In one hearing, where the FDA's position was being over-vigorously asserted by government counsel, the examiner, in connection with his regular duties as an attorney, was a subordinate of the government counsel. This, of course, did not make sense, even taking into consideration the shibboleth that the proceeding was "quasi-legislative" or "rule-making" rather than "quasi-judicial." The use of terms such as these does not help, and does not reach the problem. If it is a fact of life, as it is, that the hearings ordinarily are extremely

adversary in character, the government being a zealous adversary (and anyone who has dealt with food standards hearings knows this to be true), basic fair play was violated by the situation I have mentioned. And the situation is not fundamentally changed by shifting examiners who have spent all their professional lives as lawyers for the FDA to the Office of the Commissioner. This, as the record discloses, is a change in form and not in substance.

Let us look at it in another way. Could it possibly hurt government, industry, or the consuming public to have as examiners those who are not intimately affiliated with the agency issuing the regulations? We should be most concerned with the public and not with industry. But as far as the public is concerned, would it not be to its definite advantage to have as examiners, even in so-called rule-making proceedings, men who are sitting virtually as judges to conduct the hearings in a fair and unbiased manner. At least a faltering step forward in this direction would be the placing of all examiners of the Department of Health, Education, and Welfare in the Office of the Secretary. They would preside at all hearings of any bureau of the Department, including the FDA.

I have mentioned the necessity for fairness with respect to all proceedings. Bias on the part of an examiner is not a good thing in a governmental hearing, whether the hearing is labeled quasi-judicial or quasi-legislative. This bias evidences itself in different ways—for example, perhaps the subconscious position of an examiner that every government witness is telling the truth and that every witness who opposes any proposal of the government must necessarily be venal, corrupt, an extremist or improperly motivated. This underlying bias may reveal itself constantly through the course of a hearing so that an examiner may act virtually as senior counsel for the government.

Thus, in one hearing which extended over an inordinate period of time, almost every witness for the government was thanked by the examiner at the conclusion of his testimony and yet not one opposing witness received an appreciative word for testifying. These latter witnesses included the Chairman of the Department of Nutrition, Harvard School of Public Health, and the Chairman of the Department of Biochemistry and Director of the Division of Nutrition, Vanderbilt University School of Medicine. It is interesting to note, also, that on cross-examination, witnesses of this calibre were asked whether they were getting paid for testifying.

Ex parte meetings in the course of a hearing are likewise not a good thing, again notwithstanding that we choose to use a label to the

effect that the proceeding is rule-making. In my opinion, even the appearance of bias and unfairness should be avoided in any hearing where the government is a party.

Commissioner Elman, of the FTC, made the point succinctly in a recent dissenting opinion in connection with FTC proceedings where, in the midst of a bitterly contested hearing, an official, who appeared to be an active member of the respondent's defense team, came to counsel for the Commission with an offer to switch sides. Commissioner Elman stated, with regard to this, as follows:

"In my view the Commission's disposition of this case should be governed by fundamental consideration: its obligation to maintain public confidence in the fairness and integrity of the agency's processes and personnel. That confidence may be as much undermined by acts of apparent impropriety as actual impropriety. Government officials must look at themselves through the eyes of those on the outside; and the public's range of vision is necessarily limited. An official, in his dealings with the public, may not in fact transgress the bounds of fairness and propriety; but the public knows only what it sees, and it must be convinced of the fairness and propriety of the official's actions by what it sees. The standards of conduct appropriate for Government officials must therefore be designed to prevent not only evil but the appearance of evil; and officials must remember at all times that the appearance of things will be the basis on which they are judged by the public."

Perhaps Commissioner Elman's views stem from his prior service with the Office of the Solicitor General of the United States. Traditionally, the Solicitor General takes the position (this may be incomprehensible to the doctrinaire and over-zealous administrative official, attorney or examiner) that he represents the people of the United States, and that his function is to aid in seeing to it that justice is done, even to an adversary or to one who opposes a position taken by an agency of the government. The Solicitor General holds the view that officials of the United States should act in the broad national interest and not simply espouse unyieldingly the cause of their immediate agency; that representatives of the United States do not cut corners, do not distort the law, and must never indulge in the mortal sin of proceeding on the basis that the end justifies the means. This is not to say, by any means, that a government official should not act as a staunch and zealous advocate—of course he should—but it ill befits the majesty of the United States for officials, particularly when they are examiners, to act in a biased manner or even to give the appearance of bias.

Irrelevant Testimony at Hearings

The FDA may have created a Frankenstein monster in a recent food standards hearing. There is no question in my mind that no one

has a better right to be represented, appear, testify, examine and cross-examine at hearings than the consumer. But every one present at a hearing must be held to the general boundaries, elastic though they may be in administrative proceedings, of relevance and competence. Permitting speeches, harangues and entirely irrelevant and incompetent questioning by anyone, whether she is a consumer or a representative of industry, can serve absolutely no useful purpose and can only result in extended and costly hearings. For example, in view of the existence of the Food Additives Amendment, what relevance is there in permitting an earnest consumer to attack, in a food standards hearing, those nasty "chemicals in foods" and the alleged hazards presented by many ingredients whose safety has in fact been approved by the FDA. If an examiner is of the opinion that the Food Additives Amendment needs strengthening, I should think that he should so advise the FDA and that the problem should be taken up with Congress. It would appear, also, that all of us, even an examiner, must rely on the position taken by the FDA when, pursuant to the Food Additives Amendment, it has approved the use of various ingredients in foods.

In this connection, it also seems clear that it is entirely inappropriate for an examiner in a food standards hearing to allow testimony, examination and cross-examination attacking the statute. Section 401 specifically provides, in part, that in prescribing a definition and standard of identity for a food the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Now I can understand the position of some (without agreeing with it) that this should be changed so that in all cases every optional ingredient must be designated on the label of every food, including a standardized product. But that is not what section 401 provides. Again, if a change is desired, Congress should be asked to make one. Certainly, it is inappropriate, as well as wasteful of the time of both industry and the government, to permit an attack on the provision in a food standards hearing.

Cutting Corners on Proposal Requirement

A most unfortunate step was taken by the government in connection with the regulations for special dietary foods and vitamin- and mineral-fortified foods. This may be in line with the general viewpoint of the government that hearings are a waste of time. Since this is so, proposals are even a greater waste of time. Section 701(e)(1) of the Act provides, in language which could not be clearer, that any action for the issuance of any regulation under section 401 "shall be begun

by a proposal." To issue food standards regulations based upon a proposal dealing solely with dietary food regulations under section 403(j), and which was published four years previously, is difficult to understand. In fact, I would think that even substantially changed regulations properly pertaining to the latter section should not have been adopted, as final, four years after publication of the proposal.

Such action was presumably bottomed on the premise that, although the Congressional directive in section 701(e)(1) was clearly not being complied with, this made no difference since industry would presumably have its say at the hearing which eventually would be held. Now this sort of approach might be rationalized on the theory that it is only harmless corner-cutting when taken by industry or industry attorneys. It is perhaps old-fashioned to say, however, that we do not and should not expect corner-cutting by agencies of the United States, which are supposed to represent all of us and to act wholly in accordance with the statutes under which they work. It seems to me, however, that if we wish to discourage evasions and even avoidances by industry of the letter and spirit of our laws, including the Federal Food, Drug and Cosmetic Act, the best way of doing this is for the government itself to observe studiously both the spirit and letter of what Congress has provided.

Conclusion

I stated that I believed in food standards. I still do. But they can only serve a useful purpose and survive if they, and the procedures pursued in connection with them, are altered in many respects. If they are not, Congress or the public may finally decide that they do more harm than good. I feel like Cassandra, to whom Apollo had given the power of prophecy. Because she refused his love, however, he added to the gift the curse of never being believed. **[The End]**

Foods for Special Dietary Uses— An Historical Outline of Regulatory Aspects

By MICHAEL F. MARKEL

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WHEN IT WAS SUGGESTED that a discussion of the Special Dietary Food Regulations[1] was timely in view of the current status of administrative orders dealing with this general subject, the question arose whether such a discussion was proper in the presence of issues now formally pending before the Commissioner of Food and Drugs. In discussing this with Mr. Depew, our Chairman, we agreed that discussion should be restricted to an historical review of the administrative approach and actions in dealing with the regulatory aspects of foods represented for special dietary uses.

Presumably, I was asked to present such a review because I served as the Presiding Officer of the hearing at which the record was made on which current regulations are based. In this capacity, I participated in many of the numerous conferences held to consider the general approach to be followed in proposing regulations, and in post-hearing conferences at which questions raised by the record regarding the proposals, were considered and resolved. Much of what I have to say is based on recollections from such participation and is not found in the record.

The assignment for this review was accepted on the basis indicated. I trust the historical outline here presented will prove meaningful and enlightening to those interested in this subject, even though discussion of the current issues is avoided.

While the current controversy has raised a host of questions, it seems to me that the issues which are fundamental are not far

[1] 21 CFR, 1.11 & Part 125.

different from those raised about a quarter of a century ago. Working on this review, I was reminded of a saying here pertinent, which a good friend of mine falls back on when anyone comes to him to spill his troubles. He tells them "let me tell you my troubles and we will have discussed yours." In recalling some of the deliberations of twenty-five years ago and in checking back into some of the old records, it appears, indeed, that a discussion of the questions then raised will be a discussion, in many respects, of questions which are current and basic in the orders under attack. Whether the conclusions then reached remain valid today remains to be determined in the current proceedings.

However, there is one highly important difference in the factual basis for the administrative action taken in 1940 with respect to certain issues and the expressed basis for administrative treatment of the same issues in the orders under attack.

In 1940, the approach was considered and planned on the basis of recognized existence of widespread nutritional deficiencies, a fact of considerable concern to both Government and nongovernment experts interested in the matter of nutritional needs.

The provisions in the orders under attack which appear to be most controversial are, on the other hand, based on just the opposite alleged facts; namely, that no general nutritional deficiency exists today, and that such as does exist is in isolated cases under conditions which are not general, but are, most likely, attributable to a restrictive nutritional environment or nutritional habits of the individual involved. This remains to be established as the fact at a formal hearing, I presume.

If the non-existence of general nutritional deficiencies is established as the fact, it will, of course, call for quite a different treatment of the subject matter from that rested on the existence of widespread nutritional deficiencies. However, notwithstanding this important difference, many of the fundamental questions raised now were raised in the prior hearing. Therefore, a review of these old issues and a look at how they were resolved should serve to shed some light on the current controversy.

The question of how to approach the problem of dealing with recognized nutritional deficiencies within the statutory authority included in the 1938 Federal Food, Drug and Cosmetic Act was the subject of careful and extended deliberation by the administrative officials charged with the responsibility of administering the Act. These deliberations involved many informal conferences between ad-

ministrative officials and persons of the scientific community recognized as specially qualified to advise, as well as members of the regulated industry. Since this review includes discussion of some matters not found in the records, but based on recollections of what took place, it is deemed desirable that some of the leading participants be identified in order to provide a basis for evaluating the soundness of the administrative actions, as recalled.

Participants in 1940 Hearing

The person having the principal and ultimate responsibility in the matter was, of course, the then Chief of the Food and Drug Administration (FDA), now called "Commissioner," the late Mr. Walter G. Campbell. He was, in my opinion, the greatest Commissioner of Food and Drugs since the enactment of the original Federal Food, Drug and Cosmetic Act.

In saying this, I am not unmindful of all the laurels heaped in this respect upon Dr. Wiley. He is deserving of them and he, indeed, *is* the father of the Federal Food, Drug and Cosmetic Act. However, Dr. Wiley was a crusader; and it took a crusader to bring about that legislation. Nevertheless, he remained a highly controversial figure, not only throughout his Government career, but also following his retirement from Government. He continued to publish articles in a leading magazine of the day of a nature highly critical of the regulated industry, and, in doing so, no doubt engendered considerable suspicion among the consuming public regarding the integrity of members of the regulated industries and of their products.

Not so Mr. Campbell. He was a statesman! During his administration, effectiveness in the administration and enforcement of the law reached an all-time high. Notwithstanding this, respect for the law, confidence in its administration and enforcement, and confidence in the regulated industry on the part of consumers also rose to an all-time high. In short, he not only enjoyed the confidence of the Congress and the consuming public, but also that of the regulated industry.

The esteem in which Mr. Campbell was held is significantly reflected by what transpired after the conclusion of his testimony given at the hearings held by the Senate Committee on Commerce on S. 1934 during the 73rd Congress. The record recites that at the conclusion of his testimony there was applause. Senator Copeland then said:

"Mr. Campbell, you are entitled to the applause you received. Your address today has been remarkable in many ways. You have made clear and

distinct, *and in a temperate manner,* the reasons why there should be greater control over food, drugs, and cosmetics."[2] (Italics supplied.)

This, then, was the caliber of man who spearheaded the approach in enacting regulations deemed necessary and suitable for dealing with foods offered to the consuming public for special dietary uses.

It might be indicated parenthetically, but with a considerable sense of pride, that Mr. Campbell was a lawyer. He was, nevertheless, highly qualified to deal with the scientific problems of his day implicit in an effective administration and enforcement of the Act.

On this team, the late Commissioner Charles W. Crawford was Mr. Campbell's right arm. He was the one who had shepherded the 1938 Act through Congress and was, therefore, entirely familiar with all the background considerations leading to the legislation now under review. Mr. Crawford was noted, among other things, for preciseness in draftsmanship of regulations which would insure achievement of intended statutory objectives.

The expert in nutrition of the team was the late Dr. Elmer Nelson and his then young associates, who since have become well known to many of this audience, Drs. O. L. Kline and Chester D. Tolle. Dr. Nelson enjoyed an international reputation as a highly qualified expert in the field of nutrition. He and his group maintained close liaison with leading nutritionists, not only in this country, but also abroad. They were actively engaged for upwards of two years in gathering evidence on the basis of which the nature of the proposals to be made were to be considered. This included collecting scientific information, data and opinions, from experts both in the United States and abroad.

Some of the United States experts who were particularly active in these deliberations included such men as Dr. Russell Wilder, a physician of the Mayo Clinic, who had wide experience in treating nutritional deficiency diseases; Dr. R. R. Williams, who had had occasion to observe widespread diseases in the Philippines attributable to vitamin B deficiency and who later succeeded in synthesizing vitamin B; Dr. William H. Sebrell, Jr., then in charge of nutrition investigation for the National Institutes of Health; Dr. Philip C. Jeans, a physician of national reputation as a pediatrician who had done extensive clinical research in the field of nutrition; and others.

Such then was the composition of the group which considered the problem of nutritional deficiencies and the means whereby this problem might be best attacked.

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[2] Dunn, *Federal Food, Drug, and Cosmetic Act,* p. 1107.

In this connection, there should also be recalled an incident of interest. A young man, who was relatively new on the staff at about the lowest, if not the lowest, professional grade, participated in one of these conferences. He advocated a certain point, and, as I recall, did so aggressively and with considerable feeling. When he had finished, Mr. Campbell thanked him for his contribution, saying he would bear the point in mind, and then excused him. As the young man left the room, Mr. Campbell commented to those remaining: "There is a refreshing youngster from whom we may expect a great deal." This youngster's name was Goodrich—William W. Goodrich, who was then preparing the evidence for presentation at the flour hearing, a proceeding pertinent to an overall discussion of this subject, as will become apparent.

The Problem of Nutritional Deficiencies

The focal point of all these discussions in the preparation for the hearings was the recognition of the then existing nutritional deficiencies as reflected by the existence of rather widespread nutritional diseases. Aside from these nutritional considerations, the underlying question was how this problem might be attacked most effectively within the scope of administrative authority granted by the new Act.

There was another development in the Department of Agriculture, of which the FDA was then a part, collateral to the indicated preparation for issuing a regulation under Section 403(j),[3] which had a direct impact on the regulatory approach to dealing with foods represented for special dietary uses. This was the Department's concern over the general inadequacy of the diet. The then Undersecretary of Agriculture, Mr. Wilson, felt very strongly that the Department had a responsibility to do whatever could be done to ensure a more adequate general diet. This pressure from the Secretary's office grew stronger as more and more information was received showing the extent of the existence of dietary deficiencies, particularly in the Southern States. This all came to a head during the course of the hearings on the special dietary food regulations, as will appear a little later.

In considering the type of regulation indicated, note was taken of the then existing industry practices in marketing various types of products recommended for use as nutritional adjuncts. It was noted, and later reflected by records made at hearing, that over the past

[3] 21 U. S. C. 343(j).

decade, the 1930's, the sale of a variety of formulations of concentrates and of foods to which concentrates had been added, was widely and intensively promoted on the basis of their claimed nutritional value. When added to foods, these concentrates were added in widely differing combinations and amounts.

For example, it developed in the flour hearing, which overlapped with the hearing of the special dietary food regulations, that there were then being marketed six brands of flours containing added nutrients, each differing from the other in the nutrients added, both qualitatively and quantitatively. These included, one with added vitamin D only; the second with added calcium only; the third with vitamin B_1, nicotinic acid and calcium; the fourth with added vitamin B_1, calcium and iron; the fifth with added wheat germ and wheat germ oil; the sixth with vitamin B_1, riboflavin, calcium and iron. Also marketed then were two brands of enriched farina. One contained added vitamin B_1, calcium and iron and the other only added vitamin D. The latter is the brand, of course, readily recognized by many of this audience because its producer challenged the validity of the standard in the celebrated "Farina case."[4]

The claims made for such products and such fortified foods were then regarded by the group as being highly exaggerated and inclined to be misleading in that they consisted mainly of generalizations. Very little information, nutritionists complained, was given with respect to the actual nutritional value of the products and the manner in which they should be used to achieve the intended dietary benefits.

On the basis of these considerations, it was ultimately concluded that the indicated problem of nutritional deficiency could be dealt with adequately only by a two-track approach, as it were; namely, (1) consumer education; that is, by issuing regulations under Section 403(j) which would prescribe the information required to be placed on the labels of foods falling within the purview of such a regulation; and (2) by issuing standards under Section 401[5] for certain basic foods in which the kinds and amounts of the added nutrients would be fixed.

While the overall problem had been under consideration and discussed over a considerable period, this concept did not fully crystallize until the hearing on the special dietary food proposal was under

[4] *Quaker Oats Co. v. Federal Security Administrator*, 318 U. S. 218, 63 S. Ct. 589 (1943).

[5] 21 U. S. C. 341.

way and the flour hearing, previously commenced, was in recess.* It was at this point, and after the state of industry practices in adding nutrients to flour, as earlier indicated, had come to light and Dr. Nelson's very extensive testimony in the hearing on the special dietary food regulations was on record, that the two pressures for administrative action, the one to provide adequate information and the other to improve the general diet, merged.

It was during the flour hearing recess while many outstanding experts were in Washington for the hearing on the special dietary food regulations, that the concept fully ripened. Dr. Kline recalls that there were many earnest and extended "hallway" discussions between experts representative of all areas of interest, Government, the scientific community and industry, and particularly those of the flour industry, since the question of a realistic plan for fortifying flour had now become an important part of these discussions.

In the meantime Undersecretary Wilson was *really* pressing for an improvement in the basic diet. Rational fortification of flour seemed to be a good starting point. The upshot was that members of the group organized informally and agreed to discuss the matter first with Undersecretary Wilson.

Loosely organized as the group was, it appeared that Dr. Wilder emerged as the spokesman for the scientific community; Mr. Charles Wesley Dunn was one of the leading spokesmen for the food industry in general; and Mr. Cullen Thomas, an official of General Mills, was the principal spokesman for the milling industry. FDA officials were invited to attend their meetings. The discussions with Undersecretary Wilson led to the suggestion that the group discuss the matter with the National Academy of Sciences to determine possibilities of a more formal organization in that body. This was done. The result was establishing the Food and Nutrition Board of the National Research Council. This Board then played an important role in the formulation and adoption of the indicated approach.

Such then is the historical background of the administrative action ultimately taken in issuing special dietary food regulations and enriched flour standards. It should be noted, therefore, that there is nothing novel in approach in dealing with foods represented for special dietary uses by proceeding under both Section 403(j), to the

* The flour hearing commenced on September 9, 1940; recessed on September 17 and was resumed on November 12. The hearing on the special dietary food proposal commenced on October 7, 1940 and was concluded on November 1.

extent this is necessary to provide information deemed necessary to fully inform consumers, and under Section 401, to fix the nutrients, qualitatively and quantitatively, in foods offered for special dietary uses.

Discussions and Decisions

A look at some of the questions which arose as a result of the action taken by following the indicated approach, and the manner in which they were resolved is essential to this historical review. This suggests examination of statutory language of both Sections 403(j) and 401.

The legislative history of Section 403(j) is rather sparse. True, there are many references to it during the course of congressional consideration of the 1938 Act. However, every successive explanation of its purpose was, in essence, repetitive of what had been said before. A representative statement of the purpose of the section cited from the legislative history in several industry briefs is the following:

"Paragraph (g) [j] deals with articles offered for special dietary uses, such as infant foods, invalid foods, slenderizing foods, and other dietary products intended for special nutritional requirements. It authorizes the establishment of regulations * * *."

It was, therefore, necessary to determine the meaning of the statutory language in the presence of conditions as they existed when the administrative action to promulgate regulations was being considered.

The first question which appeared to suggest itself to all concerned the kinds of food which would be subject to whatever regulation might issue. It was deemed necessary to have a reasonably specific conception of the kinds of food which would be subject to any regulation which might issue, in order to consider, realistically, what label information should be required by regulation which would adequately inform consumers. This indicated the need for issuing an interpretive regulation.

No "evidence," in the statutory sense, was required to consider such a proposed regulation. A proposed general regulation was included in the notice of hearing to receive evidence on the proposal for the substantive regulation. While no evidence was required, comments were invited at the outset, because it was deemed desirable that all participants in the hearing of the substantive regulation come to some reasonable conclusion as to the type of products to which those regulations should apply. Therefore, the hearing was divided into two parts.

The interpretive regulation was considered informally and comments were invited. They were slow coming. The record shows that several recesses were directed by the Presiding Officer with exhortations that the parties discuss the matter among themselves and come forward with helpful comments. Initial statements were not at all helpful. What sparked off an issue which eventually proved to be one of the two most controversial, was a brief filed by a chain grocery store suggesting that vitamin and mineral concentrates, whether in pill form or otherwise, be regarded as foods, hence subject to that regulation. Reference was made to an Indiana court decision which had held that vitamin pills were foods and that their sale in a grocery store did not violate the statute forbidding the sale of drugs in grocery stores.

The National Association of Retail Druggists was the first to respond to this brief, contending the contrary, and pointing out that the Indiana decision was on appeal and that they had every expectation that it would be reversed. Later other interested parties came in on both sides so that the question of whether vitamin and mineral concentrates and other nutrients sold in concentrated form were to be subject to the labeling requirements of the regulations became highly controversial.

In essence, the one side argued that vitamins and minerals were nutrients present in foods consumed by humans and were, therefore, foods regardless of the form in which they were supplied to consumers. The drug industry, and others, argued, on the other hand, that these were special preparations produced by artifact, many by synthesis, similar to processes followed in producing drugs; that they were packaged like drugs; marketed like drugs and were, therefore, regarded as drugs by consumers, wherefore the drug labeling requirements should apply.

However, since this was only interpretive regulation and since, in those days, the concept of judicial review of interpretive regulations had not yet ripened to the degree it has today, neither side contemplated doing anything regarding that issue until such time when enforcement of the substantive regulation was undertaken. Nevertheless, conferences with the Commissioner's office were continued after the substantive regulation had issued. The question of application of that regulation to vitamin and mineral concentrates was discussed repeatedly and at length by both sides, but particularly by the major drug industry.

There is nothing to be found anywhere in official communications, including the trade correspondence letters which were then issued, to shed any light on the final resolution of the question. However, it is the fact that the administrative officials drew a line of demarcation between concentrates of nutrients, such as vitamin and mineral preparations, represented for use as dietary supplements, and the high potency products which exceeded the minimum daily requirements prescribed in the regulations by threefold or more. The "three to five" times the minimum daily requirements suggested as a therapeutic dose of vitamins and minerals was on recommendation of the Council on Food and Nutrition of the American Medical Association.

Labeling Requirements

Industry was informed that any vitamin preparation falling in the first category would be regarded as a food subject to the substantive regulation and the high potency products would be deemed to be drugs and could be labeled as required by the drug regulations. To the best recollection today of those having been involved in this, that was the way the matter was left. Nothing was published and apparently both parties marked time to await further developments.

Further developments were soon to come. They were that the drug industry elected voluntarily to comply with the mandatory labeling requirements of the substantive regulation, regardless of product potency. One can only speculate as to the reason for this sudden change. However, informed speculation appeared to be that someone finally got the lawyers out of their law libraries and introduced them to their sales managers and the marketing people. The grapevine had it, that the marketing people were delighted to market their products with label statements that their concentrates, when taken as directed, provided three, four or five times the minimum daily requirement of the vitamins and minerals contained in their formulations. In short, complying with the regulation was regarded as a positive sales approach rather than the crepe.

In retrospect this appears to have proven a blessing in disguise. Had it been ruled then that high potency vitamin and mineral concentrates were drugs, *per se*, hence subject to drug labeling requirements, and considering the conditions for which they are needed in the light of administrative rulings with respect to self-diagnosis of diseases, it is safe to speculate that compliance with Section 502(f)[6] of the Act would have relegated most, if not all, high potency vita-

[6] 21 U. S. C. 352(f).

mins to the prescription drug category and their sale might well have been restricted accordingly today.

In the practical administration of the section and the regulations promulgated under it at this time, dividing lines are drawn between foods which are represented as being good sources of the specified nutrients, foods represented for special dietary uses, including concentrated nutrients, and products which are regarded as drugs by reason of the representations made for them. The application of these lines of demarcation to specific products is somewhat thorny and becomes difficult in borderline cases. In general, however, representation that orange juice, for example, is a good source of vitamin C is not regarded as a representation of the food for special dietary uses. Concentrated nutrients represented as dietary adjuncts which will suffice to prevent occurrence of nutritional deficiencies in the factors, present in the formulation, are regarded as foods represented for special dietary uses, hence subject to the labeling requirements of the regulation, regardless of potency. If, however, that same formulation is represented as providing the identical quantities of the nutrients, but then goes on and says that this is adequate to prevent the occurrence of scurvy, pellagra or beriberi, as the case may be, such a representation then represents the product as a drug which must be labeled as such. It also raises a question of misbranding if it suggests prevention or correction of specific diseases which do not exist.

Quite a number of statements were filed suggesting various definitions of the term "food for special dietary uses." It was apparent that most of the objections to the proposed regulations were based on the fear that any dietary claim for any food which might be a source of particular nutrients became subject to the requirements of this regulation. Indeed, the milk industry argued rather extensively that the regulation should contain an express exemption for milk.

The fallacy in most of these arguments was that they took off from a point looking at the nature or the composition of the food. This may have been occasioned by the fact that the proposed general regulation, itself, recited the condition under which a "food" would be subject to the substantive regulation. The regulation, as issued, however, does not define the term "special dietary food" but rather the term "special dietary uses." This then squares with the fact that the section concerns itself with labeling and that the nature of the food does not, *per se*, bring a product within the purview of these regulations. It is the *representation* made for a food, either by words,

or by labeling or, by other means which serve to create specific concept in the consumer's mind suggesting that the food has value for special dietary uses.

Another controversial issue arose out of this very concept. It seemed that during the course of the hearings the language of the proposed interpretive regulation was more critically analyzed. Thus about the middle of the hearing additional comments came in and subsequent briefs were filed suggesting that the words "on the label" be inserted in the proper places so that the regulation would read that any food "purporting to be or being represented *on its label*" for special dietary uses should be subject to the regulation. This led to rather extended discussions of the question of jurisdiction of the Secretary to base enforcement of any regulations in his area of jurisdiction on what might be said in advertisements.

This argument was rejected on the ground, to the best recollection, that the term "if it is represented" appeared not only in Section 403(j) but in other sections of the Act, none of which were intended to be construed that narrowly. It was felt that if the Congress had meant to say "if it is represented on the label" it would have inserted those words. Since the words did not appear in the statute, any regulation inserting those words, without reasonable factual basis for such a restriction, would amount to an attempted modification of statutory language by administrative regulation. It should be recalled that this question was finally litigated in another area and that the courts have sustained the position then taken.

Enriched Flour Standards

Some of the specific questions raised with respect to the enriched flour standards, which may have a bearing on current proceedings, also represent historical background in the general area of dealing with foods represented for special dietary uses. This requires consideration of pertinent provisions in Section 401 of the Act as then applied. As noted earlier, the concept of improving the basic diet by adding nutrients to basic foods was approved by the Food and Nutrition Board. How this was applied to flour is apparent from the report by the Presiding Officer, Mr. Alanson Wilcox, now the General Counsel of the Department of Health, Education and Welfare, who eloquently summarized the state of the record in its pertinent parts, as follows:

"While the record does not show the claims made on behalf of these various commodities in advertising and labeling, it seems self-evident that even wholly

honest statements in regard to products so diverse must prove confusing to all but the most well-informed of consumers. The fear of honest producers that in the absence of strict regulation they will face dishonest competition also appears justified.

"It is submitted that the following proposed finding is fully warranted by the record:

'36. There have recently been placed on the market flours and self-rising flours enriched with one or more of the nutritional elements referred to above. These flours vary widely in composition. Unless a standard is promulgated which limits the kinds and amounts of enrichment, the manufacturers' selection of the various nutritive elements and combinations of elements on the basis of economic and merchandizing considerations is likely to lead to a great increase in the diversity, both qualitative and quantitative, in enriched flours offered to the public. Such diversity would tend to confuse and mislead consumers as to the relative value of and need for the several nutritional elements, and would impede rather than promote honesty and fair dealing in the interest of consumers.'

"To meet this situation the proposed regulation would permit none of these elements as optional ingredients in flour, bromated flour, phosphated flour, self-rising flour or farina, but would establish separate identities for 'enriched flour,' * * * which would be required to contain vitamin B_1, riboflavin, nicotinic acid and iron, and in each of which vitamin D and calcium would be optional ingredients."

There is no need for a detailed discussion of the legal questions raised by the order embodying this recommendation. Most members of this audience are familiar with the Supreme Court decision in the "Farina" case[7] in reviewing that order. However, I strongly recommend that those not familiar with this case, who have an interest in the current proceeding, carefully read and understand it, because much of what the Court said there is highly pertinent to questions currently at issue.

It will suffice, for present purposes, merely to take note of the argument most seriously pressed against the standard. This was, in essence, that the statutory concept of "honesty and fair dealing in the interest of consumers" did not authorize the exclusion of a wholesome and beneficial ingredient from a food as long as that food was properly labeled.

The sweeping language used by the late Chief Justice Stone in rejecting this argument bears careful study by anyone interested in the historical background of development of regulatory requirements in dealing with foods offered for special dietary uses. Indeed the entire opinion provides highly significant historical background to any plan dealing with foods offered for special dietary uses.

This then outlines the historical background to the basic principles upon which administrative action has been taken in dealing with such foods.

[7] See footnote 4.

Current Controversies

While it is not the purpose to discuss issues raised by objections to the orders presently under attack, as stated at the outset, note may be taken, however, of some of the issues which appear to be most controversial, with a view of determining whether past administrative action implicit in this historical outline has any bearng on these.

There appear to be three such issues which might be noted, namely, (1) whether the statute authorizes grouping of foods of different identities in one standard; (2) whether statute authorizes "partial standardization"; and (3) whether grouping of concentrated nutrients, as such, qualitatively and quantitatively, is authorized by Section 401.

Some have argued that statutory authority for grouping foods in a single standard does not exist because it authorizes promulgation of standards only for "any food"—singular. The argument does take note that provisions of the same section in referring to optional ingredients, includes the term "any food or class of food." It is argued, however, that the words "class of food" remained in this section through inadvertence and should have been deleted. Some past administrative actions, which should be noted, may or may not have a bearing on these issues.

The closest we come to a regulation establishing a definition and standard of identity for "a class of food" is the standard often referred to as the "omnibus vegetable standard."[8] The list of vegetables included in that standard can certainly not be said to be of the same identity because they do differ significantly from one another as vegetables. No one raised the question at that time that a separate standard be written for each kind of vegetable. Since then, however, it has become necessary to remove certain specific vegetables from the omnibus standard and write a specific standard for several because of the special circumstances arising in the development of food technology, which required standardization of factors peculiar to the individual vegetables.

The canned fruit standard is another standard of this nature. It does not undertake to identify each and every fruit. It fixes only the factors common to all, primarily the several prescribed packing media and optional ingredients. In prescribing packing media this standard does take note of differing characteristics of the different fruits in that it specifies different density ranges for some fruits than it does for others.

[8] 21 C. F. R., Sec. 51.990.

Other similar examples of administrative action might be cited. However, this will suffice for purposes of historical background.

The question then is first whether such past administrative action is a valid exercise of administrative authority, notwithstanding the fact that it has not been questioned, as such; and, if valid, is Part 80.2 of the order under attack distinguishable in basic principle from these past administrative actions?

The examples cited may also have some bearing on the question of "partial standardization." As noted, in each of these standards, only certain factors were fixed. They do not undertake to define spinach, carrots, peaches, cherries, and the like, nor fix any factor with respect to any of these, as such. The standards merely fix factors of common application, principally sirup densities and optional ingredients.

Assuming, for purposes of discussion of this point, that the Secretary had seen no reason for defining flour and bread, as such, and assuming also he had then issued a standard providing merely that enriched flour and enriched bread were such foods when they included the specified added concentrated nutrients in the amounts indicated, would this have led to a different result in the "Farina" case in the light of facts as summarized by the Presiding Officer? The resolution of the so-called "partial standardization" argument should provide the answer to this question.

Part 80.1 raises a third question, namely, whether Section 401 authorizes standardization of vitamins and minerals, as such, which are offered as dietary supplements by circumscribing them qualitatively and quantitatively to the exclusion of any other grouping. The validity of that order depends, it would seem on whether there is a difference in basic principle, from the standpoint of "honesty and fair dealing in the interest of consumers" between providing these nutrients to consumers so circumscribed as optional ingredients in their flour and in their bread to achieve the intended dietary use and in providing the same nutrients to consumers, as such, identically circumscribed and offered for the identical dietary use. In short, is there a difference in principle between asking consumers to eat their vitamins and minerals *in* their bread or *with* their bread? Interesting questions these! We shall await the answers with great interest.

That is the way it was, and that is the way they did it, a quarter of a century ago. **[The End]**

Product Liability—1966

By WILLIAM J. CONDON

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IT WILL, I AM SURE, COME AS NO SURPRISE to anyone that the area of principal emphasis in this report involves the development of the doctrine of strict liability in tort. No less than nine jurisdictions entered the ranks of those which have accepted this doctrine. For anyone who is keeping a box score, these nine are Connecticut, Kentucky, Missouri, Mississippi, Nevada, Ohio, Oklahoma, Pennsylvania and Tennessee.

Trend Toward Acceptance of Strict Liability in Tort

You will note that this list includes Mississippi, which was the only state which had not accepted the principle of *McPherson v. Buick Motor Car Company,* 217 N. Y. 382. In spite of this, the Mississippi Court found itself pursuaded by the principle of Section 402A of Restatement of Torts, Second.

Connecticut not only adopted the doctrine of strict liability but, within a few short months, extended it to cover an innocent bystander. In this case, *Mitchell v. Miller,* CCH PRODUCTS LIABILITY REPORTS ¶ 5508, the bystander was innocent in the strictest sense of the word. The action was against an automobile manufacturer for injuries which resulted in the death of plaintiff's husband because of a defect in the transmission of an automobile manufactured by the defendant. The owner of the car had parked it in the parking area of her country club, leaving the transmission in the "park" position. Because of a defect in the mechanism of the car, this failed to lock the transmission and permitted the unmanned car to roll down an incline and strike the decedent as he was playing golf on the 17th fairway. Without so much as indicating what kind of a round the decedent was having, the Connecticut Superior Court permitted plaintiff's action for strict liability to be maintained against the manufacturer of the automobile.

The adoption of the strict liability theory in Pennsylvania had a rather unusual twist. The Court handed down decisions in two cases on the same day, both written by the same Justice. In the first of these, *Miller v. Preitz,* CCH PRODUCTS LIABILITY REPORTS ¶ 5571, strict liability was held not to be available to the plaintiff because the action was founded in warranty and privity was held to be a requirement to sustain an action by his purchasers against remote vendors. In the second case, *Webb v. Zern,* CCH PRODUCTS LIABILITY REPORTS ¶ 5572, the Pennsylvania Court adopted the doctrine of strict liability in tort and made it available to the plaintiff because he had brought his action in trespass. In other words, in Pennsylvania the action must be framed in tort in order to sustain the application of the strict liability in tort theory. This is somewhat ironic since all the cases relied upon in the Restatement to support Section 402A were warranty cases.

This change in the law of Pennsylvania was not accomplished without a violent and anguished dissent by the Chief Justice of that Court. Some of his language was calculated to warm the cockles of the heart of a died in the wool defense lawyer. For example:

> Today, no one knows from month to month or whenever the Supreme Court of Pennsylvania or the Supreme Court of the United States meets, what the law will be tomorrow—or, by retrospectivity, what the Court will now say it always should have been—or what anyone's rights, privileges, liabilities and duties are. The net result is uncertainty, confusion, dismay, and constantly DIMINISHING respect for Law and for our Courts—and, of course, is one of the major causes of the constantly and rapidly increasing litigation which is literally swamping our Courts.

It should be noted as well that the adoption of the strict liability doctrine in Ohio, *Lonzrick v. Republic Steel Corp.*, CCH PRODUCTS LIABILITY REPORTS ¶ 5578, was also accompanied by a vigorous dissent by the Chief Justice of Ohio's Supreme Court. The burden of Chief Justice Taft's argument is that a revolutionary change in the law of this magnitude is properly within the province of the Legislature, not the Courts.

An Example of *Strict* Liability

It has been pointed out many time here, as well as elsewhere, that manufacturers and sellers of products are not necessarily rendered defenseless in a strict liability jurisdiction. Plaintiff must still show that the product was in a defective condition, unreasonably dangerous to the user at the time it left the defendant's control. This leaves the plaintiff with the important substance of the burden which he has

always carried, and, as I am sure will be brought out in the drug discussion which will follow this paper, the mere fact of injury following use is not sufficient to sustain this burden. With this in mind, it is extremely disturbing to come upon a case such as *Pulley v. Pacific Coca-Cola Bottling Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 5591, decided by the Supreme Court of Washington. This case involved injuries sustained as a result of drinking a beverage from a bottle which was alleged to contain the remnants of a cigarette. At the trial, defendant bottler sought to show the methods used in its plant to prevent contamination of its products by foreign objects or material. This evidence was excluded by the Trial Court on the ground that it was irrelevant in an action for breach of warranty. The Supreme Court of Washington affirmed the decision of the Trial Court and upheld the exclusion of the proferred evidence. In its opinion the Court said this:

> An assertion of breach of warranty by a consumer-plaintiff, and that he or she was harmed by the presence of some foreign object in food or drink, in practical effect thrusts a burden upon the defendant manufacturer and the defendant retailer to show who contaminated the particular food product—and will not permit a showing by indirect and circumstantial evidence that it was improbable or even impossible that the defendants were responsible for the presence of the harmful object.

Now, this is what I call *strict* liability. Defendant not only is precluded from raising a fact question by showing that it was highly improbable that the defect was in the product when it left his control. According to the language used by the Court, defendant would be precluded from showing that it was impossible that the defect was in the product when it left defendant's control. The effect of this holding is to render the manufacturer an insurer that his product may be used with safety irrespective of what may happen to it after it leaves his possession and control, unless he can show by direct evidence who produced the contamination.

As always, the PRODUCT LIABILITY REPORTS are not confined in their appeal to serious students of the law, nor are they without their human interest side. As proof of this we have but to consider the sad tale of Orlando of Pensford, *Young v. Kal-Kan Foods, Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5592. The Court tells his story so much better than I could that I defer here to Mr. Justice Bonpane of the Los Angeles Superior Court:

> "Orlando of Pensford" was a champion. His distinguished pedigree emanated from Pensford Cattery in England, one of the most famous in the world. He was entered in 47 shows, in 44 of which he received a variety of ribbons, trophies and championship awards from at least five of the recognized cat fanciers associations.

Orlando, who was a striking figure of the feline species, had reached the pinnacle of glory when he won the award of "Grand Champion", and now, on the day of his last contest, even as the shadow of death advanced upon him, he went on to achieve added triumphs. Not only the females of the species, but cat fanciers everywhere were awed at the striking and imposing figure of Orlando.

He meant a lot to cattery, to cat fanciers, and certainly to the proud owner, as he was something unusual to behold. Orlando of Pensford was raised on a silver spoon and perhaps he felt it was such an indignity to be fed the ordinary food of the commoner that his sensitive nature could well have rebelled when he was fed horse meat, following which he was lamentably beset with a violent turbulence of his intestinal processes, the effect of which, whatever may have been the real cause, was so traumatic that he went into shock and died.

What makes the story even sadder is that plaintiff was unable to prove that the horse meat was indeed the real cause of Orlando's demise, and the death of this champion went uncompensated.

Sometimes the fact situations in product liability become so graphic that one is tempted to write a scene for a movie or some other theatrical presentation. Such a case is *Archote v. The Travelers Insurance Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 5510. Plaintiff was a sport, and. as such, a frequent patron of the Tunnel Bar and Poolroom. On the day in question, the poolroom was busy. Plaintiff was forced to play for a while with a cue which was not as straight as it might have been. Thus, when other players finished their game and left the room, plaintiff exchanged his cue for one of theirs. He sighted it for "straight", chalked the tip and took a single hard shot. The cue stick came apart in the middle and rammed into his thumb about an inch and a half under the skin. Just imagine what Art Carney could do with a script like that.

Finally, let me just strike one blow for clarity in pleading. Lawyers are always, it seems, under attack for loose and obscure language in their pleadings, and particularly in their complaints. The reports for 1966 contain an example of the opposite type which is so clear, so plain and so obviously accurate that I chose a brief quotation from it as my terminating offering today. The case is *Haley v. Merit Chevrolet Inc.,* CCH PRODUCTS LIABILITY REPORTS ¶ 5512. In an action for injuries arising out of an accident allegedly caused by a defective automobile, we find in the complaint this language:

As they proceeded, there seemed to be a noise in the front and under the hood, and then suddenly there was a snap or clatter in the front end and the steering wheel came loose from the dashboard and dropped into the lap of the plaintiff. This caused her to lose control of the car.

Certainly, no one can charge the draftsman of that language with ambiguity, obscurity or obfuscation. Go thou and do likewise!

PRODUCT LIABILITY CASES FOR 1966

The list of cases for 1966, grouped according to classification, is as follows:

FOREIGN SUBSTANCE AND CONTAMINATED FOOD CASES

English v. Louisiana Creamery, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5523 (La. App.)

Levy v. Paul, CCH PRODUCTS LIABILITY REPORTS ¶ 5542 (Va.)

LaMack v. Fontainebleau Hotel Corp., CCH PRODUCTS LIABILITY REPORTS ¶ 5560 (Fla. App.)

Hunt v. Ferguson-Paulus Enterprises, CCH PRODUCTS LIABILITY REPORTS ¶ 5566 (Ore.)

Taylor v. B. Heller & Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5620 (C. A.-6)

FOREIGN SUBSTANCE BEVERAGE CASES

Givens v. Baton Rouge Coca-Cola Bottling Co. Ltd., CCH PRODUCTS LIABILITY REPORTS ¶ 5528 (La. App.)

Birmingham Coca-Cola Bottling Company v. Gosa, CCH PRODUCTS LIABILITY REPORTS ¶ 5532 (Ala.)

Allen v. Coca-Cola Bottling Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5563 (Ky.)

Pulley v. Pacific Coca-Cola Bottling Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5591 (Wash.)

Coca-Cola Bottling Company of Tucson, Inc. v. Fitzgerald, CCH PRODUCTS LIABILITY REPORTS ¶ 5626 (Arizona App.)

Shoshone Coca-Cola Bottling Co. v. Dolinski, CCH PRODUCTS LIABILITY REPORTS ¶ 5659 (Nevada)

BURSTING BEVERAGE BOTTLE CASES

Hood v. P. Ballantine & Sons, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5487 (U. S. D. C., S. D. N. Y.)

Rafferty v. Hull Brewing Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5515 (Mass.)

Naquin v. Baton Rouge Coca-Cola Bottling Co. Ltd., CCH PRODUCTS LIABILITY REPORTS ¶ 5551 (La. App.)

DRUG CASES

Oppenheimer v. Sterling Drug, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5502 (Ohio App.)

Cudmore v. Richardson-Merrell, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5503 (Tex. Civ. App.)

Cochran v. Brooke, CCH PRODUCTS LIABILITY REPORTS ¶ 5504 (Ore.)

Knowls v. Vick Chemical Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5536 (Ark.)

Lewis v. Baker, CCH PRODUCTS LIABILITY REPORTS ¶ 5546 (Ore.)

Russell v. Community Blood Bank, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5547 (Fla. App.)

Meyer v. G. D. Searle & Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5632 (U. S. D. C., E. D. N. Y.)

Garrett Drug Company v. Kulesza, CCH PRODUCTS LIABILITY REPORTS ¶ 5642 (Tenn. App.)

MacKay v. Crown Drug Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5644 (Okla.)

Stromsodt v. Parke-Davis & Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5645 (U. S. D. C., No. Dakota)

Sterling Drug, Inc. v. Cornish, CCH PRODUCTS LIABILITY REPORTS ¶ 5664 (C. A.-8)

COSMETIC CASES

Garthwait v. Burgio, CCH PRODUCTS LIABILITY REPORTS ¶ 5500 (Conn.)

Farnum v. Bristol-Myers Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5583 (N. H.)

Barnett v. Bailey's Beautician Supply Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5638 (Ind. App.)

Raskin v. Shulton, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5641 (N. J. App. Div.)

Pierce v. Avon Products, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5655 (Okla.)

ANIMAL FEED CASES

Southland Milling Co. v. Vege Fat, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5520 (U. S. D. C., E. D. Ill.)

McMillen Feeds, Inc. v. Harlow, CCH PRODUCTS LIABILITY REPORTS ¶ 5577 (Tex. App.)

Young v. Kal-Kan Foods, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5592 (Cal. Super. Ct.)

Primrose v. Philadelphia Dressed Beef Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5624 (U. S. D. C., E. D. Pa.)

ECONOMIC POISONS CASES

Perry Creek Cranberry Corp. v. Hopkins Agricultural Chemical Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5489 (Wis.)

Venie et al. v. South Central Enterprises, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5531 (Mo. App.)

DEFECTIVE CONTAINER CASES

Rogers v. Karem, CCH PRODUCTS LIABILITY REPORTS ¶ 5564 (Ky.)

Webb v. Zern et al., CCH PRODUCTS LIABILITY REPORTS ¶ 5572 (Pa.)

Smith v. Onachita Coca-Cola Bottling Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5588 (La. App.) **[The End]**

PROPOSED FEDERAL LEGISLATION

Among the bills, relating to food, drugs and cosmetics, introduced in the 90th Congress are the following:

Drug label compendium . . . A bill, S. 720, proposing the publication of a U. S. Drug Label Compendium by the FDA was introduced into the U. S. Senate on January 30, 1967. The compendium would contain a list of all new drugs which have been approved for marketing together with their official names and required labels. An increase of $75 for new-drug applications and $25 for supplementals was proposed as the source of funds to cover the ultimate cost of publication. On the other hand, drug manufacturers would be allowed to omit package inserts and other information from their drug products.

Labeling of prescription drugs . . . The "established name" of a drug must appear in the labeling and advertising of certain drugs sold by prescription each time the "proprietary name" is used under the provisions of H. R. 3047, a bill submitted to the U. S. House of Representatives on January 19, 1967.

Sample drugs . . . The mailing of unsolicited sample drug products would be prohibited under the terms of H. R. 3954 and 3986, bills introduced into the U. S. House of Representatives on January 26, 1967. However, an exemption is provided for such products mailed to licensed physicians, surgeons, dentists, pharmacists, cosmetologists, barbers, and veterinarians.

Training bill . . . Mutual cooperation and assistance between the federal government and state or local authorities with respect to the enforcement of food, drug, and cosmetic laws is the theme behind H. R. 3912, a bill introduced into the U. S. House of Representatives on January 26, 1967. The bill would give the Secretary authority to: (1) establish training programs for personnel of state or local authorities, and (2) contract and pay in advance for information furnished to him by hospitals or other institutions concerning the safety or effectiveness of drugs. A similar bill, H. R. 13884, was passed by the House in 1966.

The President's Message on Protection of the Consumer

The Following Are Excerpts from President Johnson's Message to Congress on Protection for the American Consumer. The Message Was Delivered on February 16, 1967.

Protecting the Public's Health

Today, we have a network of safeguards protecting the public's health.

In 1938 the Congress strengthened the Food, Drug and Cosmetics Act to require that the safety of drugs be cleared prior to marketing. In 1962, the law was further reinforced to require that the effectiveness of drugs also be cleared prior to marketing.

The value of these laws is beyond question. Nonetheless, important gaps in the law remain which should be closed now.

I recommend the Medical Device Safety Act of 1967.

Under this Act, the Food and Drug Administration would be required to pre-clear certain therapeutic materials —such as artificial organ transplants— used mainly on or in the body. In addition, the FDA will establish standards to assure the safety and performance of certain classes of widely used devices—bone pins, catheters, x-ray equipment, and diathermy machines.

In every case, the rights of the parties will be protected by fair hearings.

This new law will not apply to simple and ordinary patient care items which have withstood the test of time and are generally recognized as safe and reliable. It will not apply to an item specially ordered or designed by a surgeon or physician. Nor will it inhibit the research and development essential to the advancement of the medical arts. It will, however, protect physician and patient alike from devices which are dangerous and unreliable.

Assuring Wholesome Meat

For 60 years, the Federal meat inspection program has removed unwholesome and adulterated products from the Nation's meat counters. The American housewife knows she can count on the quality of inspected meat. Indeed, she may expect that all the meat she buys deserves her confidence.

Yet, millions of tons of meat are not subjected to these high standards of inspection.

It should be our goal to provide full assurance of the wholesomeness of all meat products offered for sale to the housewife. This assurance can best be developed through a Federal-State partnership for consumer protection.

I recommend the Wholesome Meat Act of 1967.

This legislation would modernize the present Federal Meat Inspection Act, a law which has been amended only once since its enactment in 1907. Under the strengthened legislation, the Secretary of Agriculture would be authorized to:

—Enter into cooperative agreements with States seeking to raise their standards of meat inspection.

—Furnish these cooperating States with up to half of the administrative cost of the inspection program and a major share of the cost of training personnel to man the program.

This legislation would greatly enhance the wholesomeness of our total meat supply.

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