VOL. 29, NO. 6 JUNE 1974

Food Drug Cosmetic Law JOURNAL

Papers Presented at the Food Drug Law Institute's Food Update XIII and Pharmaceutical Update IV

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $25; single copies, $3. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

June, 1974

Volume 29 • Number 6

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

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Remarks

By SHERWIN GARDNER

Mr. Gardner Is Deputy Commissioner in the Food and Drug Administration. His Paper Was Presented at the New York State Bar Association Annual Meeting, New York, New York, on January 23, 1974.

CONSUMERISM is an increasingly powerful force in the total economy. It touches everything from the use of natural resources to the retail marketplace; from the federal budget to the U. S. Supreme Court. It should be said at the outset that I do not define consumerism in the fairly narrow context of activists or aroused citizen groups. To me, consumerism is far broader. It is now and will continue to be an integral part of the development of the evolving body of law which offers increased and needed protection to individuals and organizations in a world of growing complexity.

A century ago, small manufacturing firms and neighborhood merchants and craftsmen began to disappear. They were replaced by large corporations with nationwide systems of marketing and distribution systems which opened gaps between buyers and sellers that seemed to grow wider every year. The modern consumer movement began when Americans realized they no longer had access to the persons responsible for the quality of goods and services. Instead, they were dealing with a bureaucracy—one that doesn't often get recognized as such.

Modern technology and mass production of consumer goods was, therefore, a *societal* change which created the need for laws and regulations governing the behavior of society in the affected areas.

That is, after all, one function of law—to provide assurance and protection in a complex situation.

The Escalation of Consumerism

Consumerism may have begun a century ago, but it has clearly been greatly accelerated within the past decade. Laws now exist at all levels of government which help to protect consumers from unsafe products, and give them access to more truthful information about these products, even the conditions of sale. Courts continue to broaden the rights of individuals and groups to seek legal action against manufacturers of goods that are unsafe or are unfairly and dishonestly marketed.

As consumerism has become a new and powerful force in the marketplace, government agencies have constructively responded to rightful demands by the new consumer movement, and have often anticipated what some of these demands and requirements might be. The larger function of government, however, should be to do more than react. It should be to better understand the context within which the smaller situation has developed, and then to deal with that larger context. This is especially true of the regulatory agencies, among them, the Food and Drug Administration (FDA).

Increased Power of FDA

The FDA was once little more than an inspection agency with certain police powers which it exercised with varying effectiveness. It is now a scientific, regulatory agency that draws on expert talent from throughout the country to assure the safety of the nation's food and drug supplies. Congress has given the FDA new authority, which has greatly increased its responsibilities. Previously, the FDA operated behind a screen that kept the public removed from the Agency, whereas today it is open not only to public scrutiny but also to public participation in its decision making. Most of these changes have occurred within the past five years.

In the course of making these changes, many bureaucratic traditions have been discarded. Such traditions tend to accumulate in a bureaucracy, even as the outside world may be changing. Bureaucracies, of course, exist in government, industry and elsewhere, and all must, from time to time, undergo fundamental revision. The Food and Drug Administration has recently accomplished this revision,

again, in a process accelerated by the new consumerism. The FDA which has emerged is appropriate to the times, just as the earlier style of the Agency may have been what those times required.

Such changes have been taking place in other regulatory agencies. A new sense of public awareness and accountability is one particular effect which the new consumerism has had on such agencies. It is, perhaps, a rediscovery of purpose.

Regulation in this age of consumerism is a new situation to industry and government. We find ourselves performing in the public arena, under the watchful eye of a citizenry that is increasingly insistent, skeptical and sophisticated. An era of insularity has ended for us all.

Public Participation Encouraged

There is a basic principle which underlies the changes in regulatory attitude within the Food and Drug Administration. It is an intended, purposeful movement to open the deliberations of the FDA to greater public scrutiny, public accountability and public participation.

The FDA is engaged in an effort to encourage broad participation in the formulation and implementation of its regulatory judgments. This goal will not be achieved overnight; and it requires cooperation from all elements of the public—including industry, consumers, academicians and the professions.

A cornerstone of our approach is, obviously, the Freedom of Information Act of 1966. Prior to its enactment, there was no law dealing with the obligation of the federal government to make data in its files available to the public. Many statutes protected the confidentiality of specified data received by federal agencies, and of trade secrets and other information submitted to the government. The FDA and other government agencies had historically considered data and information they received to be confidential, and not subject to disclosure to the public, because of these long standing restrictions.

The Freedom of Information Act was a fundamental change because it stated that every document in government files would be made public unless it fell within one of nine specific exemptions (which need not be detailed here). Like most other agencies, the FDA did not hasten to implement the provisions of that Act, and, except for certain requests by the news media, there were few demands for access to the files. Court challenges later changed this, but for the

first three or four years, government largely ignored the Act. The old ways of doing business continued to prevail.

Reluctancy to Open Files

Within FDA there are perhaps two reasons for this. One was a sincere concern that important trade secrets might inadvertently be revealed, which could have grave consequences. This concern still exists, causing the Agency to take every precaution to prevent disclosure of legitimate trade secrets.

There was, beyond this, the belief that release of information on which the FDA had based its decisions would permit endless second guessing by every dissatisfied critic of that decision. Rather than waste Agency resources in such debate, with a possible loss of public confidence and an increase in public confusion, it was thought best to maintain the tradition of confidentiality.

There were good reasons for this line of thought. Behind almost all FDA actions lie complex, unresolved scientific issues on which the scientists themselves cannot reach agreement. The FDA must assemble and evaluate conflicting evidence. Although data may not be complete, the FDA cannot wait for a scientific millenium and the resolution of all the issues. It must make a judgmental decision which is properly protective of public health and safety.

It was clear, however, that maintaining confidentiality for the purpose of Agency operation was not justified, and the FDA has now set about to make full disclosure of the nonconfidential information in its files, and also of the scientific issues which surround Agency actions and decisions. The transition will not be easy. There is honest disagreement as to what may and may not be released. The Agency is pushed from one direction for greater disclosure, from other directions for less. Nevertheless, the FDA is moving in the direction of full disclosure.

I'm sure you are aware that the Food and Drug Administration is one of the largest depositories of private scientific research data in the world. We receive literally mountains of information on the safety, effectiveness and functions of foods and drugs, medical devices and cosmetics. It is available nowhere else, in any form, and since 1938, little of it has ever been divulged. We now intend that, minus the trade secrets and the truly confidential, much of it will be available for public disclosure upon proper request.

Activating the Freedom of Information mandate is one example of the FDA's new openness in conducting public business. There are others, all intended to minimize administrative secrecy, one being the new FDA approach to publishing regulations.

Administrative Procedure Act

The Administrative Procedure Act governs the promulgation of regulations by federal agencies. It requires many things, but it does not require that statements of policy or interpretation be published for public comment prior to being adopted. In the past, the FDA has sometimes promulgated them without opportunity for comment. This was not in violation of the Act. However, we have decided that, in the future, all regulations will be promulgated with adequate time for public comment. Since this includes statements of policy and interpretation, which certainly have public input, the public should have opportunity to participate in their development.

Also, the FDA has always requested public comment on proposed regulations, and the points made in these comments have affected and often been incorporated in the final regulations, as published. However, the comments as such were not always summarized and discussed, and readers of the final regulation would have difficulty locating the changes. Both industry and the consumer have objected to the FDA that they could not always understand what had taken place, even though they might agree with its outcome. As you know, that is no longer the case. As a matter of policy, there must now be a preamble to each *Federal Register* proposal by FDA which lays out the background on which it is based.

Additionally, each final order must summarize comment made on the earlier proposed order, stating whether the final order accepts, rejects or modifies it, and must succinctly inform the public of the reasons for that decision. There were, for example, ninety-eight numbered paragraphs in a ten page preamble to the final order on procedures for classifying over-the-counter drugs. Whoever read that could follow the decision-making process in its entirety. The Agency has a responsibility to keep the public informed, and we believe that this method of informing will also improve the way in which FDA decisions are made because all substantive issues need to be addressed in a logical manner.

These preambles have become an important part of the regulatory history, similar to the legislative history which describes the background and intent of enacted legislation. They serve as advisory opinions affecting the theory and implementation of the regulations. For this reason, we plan to organize and compile these preambles as an aid in implementing our regulatory program.

"Right-to-Petition" Policy

To further open the Agency to the public, we have made it easier for an individual to petition the FDA for specified action. The Constitution provides that each citizen shall have the right to petition his government. We interpret this as applying particularly to the regulatory agencies. It is now our policy that each petition received will be filed and considered by the Agency. Then, there will be a formal written response granting or denying the request.

We realize that this "right-to-petition" policy will create both work and problems for the Agency, but we know it to be consistent with the contemporary application of law. We are prepared to live with the criticism and difficulty that opening our decision making to the public may bring, knowing that the very fact of openness should engender a sense of public trust, and hopefully, an understanding of the complex and difficult issues which surround each regulatory action.

The FDA has also set about to codify all Agency procedures, under the direction of the FDA General Counsel. This massive undertaking will produce a comprehensive document dealing with establishment of advisory committees; the filing of citizen petitions; the dissemination of draft regulations; and the entire range of administrative procedures. It will publicly establish our methods of doing business that will be further evidence of Agency commitment to the openness of operation.

I offer one final example of changed regulatory philosophy within the FDA. It concerns the importance of releasing data on food and drugs previously held confidential by the Agency.

As you know, we are engaged in a comprehensive review of the safety and efficacy of over-the-counter drugs. The determination will be made, item by item, whether products are "generally recognized as effective" or not. If anything is to be "generally recognized," however, the basis for that recognition must be readily available. General recognition cannot exist on the basis of information hidden

away in a governmental agency or in a company's files and available to no one. Therefore, the scientific basis for decisions of general recognition of safety and effectiveness must, at the proper time, be placed on public record.

Consumer Education Programs

My remarks, thus far, have been concerned with internal, regulatory changes of the Food and Drug Administration. I would also like to call attention to the consumer education programs which the FDA has established and which are increasing in content and activity. We are no longer a passive agency in the area of consumer information and education. We bring consumers into the advisory panels in advance of and throughout the performance of special programs and campaigns. This has been done with the over-the-counter drug review, with the nutrition labeling program, and other review programs now under way.

We also acknowledge a public education responsibility which goes beyond simply informing persons of FDA actions. We work closely with voluntary and service organizations, consumer groups, the news media and others to raise the overall level of understanding in those areas in which the Agency operates. We are convinced that consumer education is a balanced complement to regulation, and that neither by itself can give the American people the consumer protection they require.

The nutrition labeling program especially illustrates this. In general, the program will require that any product whose label makes specific or implied claim for nutritional value or dietary benefit must make full and clear disclosure of its actual nutritional content. Also, information as to vitamin and mineral content, caloric value, fat content, etc., must be based on standard laboratory analyses and must be presented in a form that is understandable. This program is expected to result in great changes in the food industry in the next few years.

The FDA was assisted by nutrition experts, consumer groups and others in the development of the labeling approach. However, as good as it is, the program cannot be effective if the food user and buyer does not understand it, and a national public education effort for the purpose of promoting consumer understanding of nutrition labels also will be conducted. The labeling requirements are a regulatory action which the FDA would at one time have taken as its

only responsibility. The education program, however, will make our total effort much more, bringing it closer to the needs of the consumer.

Consumerism Alters Regulation Process

I have drawn upon the Food and Drug Administration to illustrate how consumerism is changing the process of regulation. I cannot say that other agencies have been affected in the same ways or that they would have responded as we did to the rise of consumerism. In terms of personal impact on consumers, and of the size and scope of the regulated industries, the Food and Drug Administration is probably the largest and most influential of the regulatory protection agencies. We have also had the most sustained experience of any in government. We have fashioned our response—and the process is not completed—from that experience and our understanding of our responsibilities. We have come to think of ourselves as a scientific, regulatory agency whose mission is consumer protection, and we look forward to meeting these responsibilities more fully.

If I were to summarize the impact of consumerism on regulatory agencies, it would be that consumerism has become the dominant force in regulation; that it is a more responsible force than many once believed; and that its greatest effect thus far and into the future is the basic change which it has caused in the philosophy of regulation —that the public's business must be conducted in public.

[The End]

ORDER SET ASIDE FOR LACK OF NOTICE OF GROUNDS FOR PROPOSED WITHDRAWAL

A Food and Drug Administration order withdrawing approval of the new drug applications (NDA's) for Alevaire, a muco-evacuant drug, was set aside by the Court of Appeals because the order was not preceded by a notice of the grounds on which the FDA proposed to withdraw approval. The manufacturer was thereby deprived of an opportunity to submit evidence that would entitle it to a hearing, according to the court. A notice of proposed withdrawal of approval was sent to the manufacturer prior to the first of two earlier withdrawal orders, each of which was terminated when the manufacturer challenged it in the Court of Appeals. That notice set forth different grounds for withdrawal than those given at the time the third order was issued. In setting aside the third order for lack of proper notice, the court said the manufacturer should not have to guess at the grounds on which the FDA might base withdrawal.

Sterling Drug, Inc., et al. v. Weinberger, et al.
CCH Food Drug Cosmetic Law Reporter

Cosmetic Legislation: Benefit-Risk

By VINCENT KLEINFELD

Mr. Kleinfeld Is a Partner of Kleinfeld, Kaplan and Becker, a Washington, D. C. Law Firm. His Paper Was Presented at the American Medical Association Conference on Cosmetic Legislation Held on March 11, 1974 in Washington, D. C.

IN ATTEMPTING TO DETERMINE whether additional cosmetic legislation is required, one important consideration is the realization that diverse problems are involved in the testing and marketing of cosmetics. As we are aware, our skin may be damaged in several ways by cosmetics, and there is probably no ingredient which can be used without injuring someone. I think it is fair to say that virtually every cosmetic may cause some adverse reaction in some persons.

Unfortunately, it is not feasible to specify a rigid series of tests, satisfactory for all cosmetics, which will be adequate to disclose the possible incidence, for example, of local contact dermatitis, loss of hair, or eye injury. As we are aware, each new preparation must be subjected to specific tests designed by experts, which take into consideration the types of ingredients, the intended manner of use of the product, and its estimated potentialities for producing particular kinds of irritation.

Act of 1938

This is essentially the procedure employed by the responsible cosmetic manufacturers who comprise the bulk of the industry. Thus, President Roosevelt pointed out to the Congress of the United States, when the bills leading to the enactment of the Federal Food, Drug, and Cosmetic Act of 1938 were under consideration, that the great majority of those engaged in the food, drug, and cosmetic industries do not need regulation—that "they observe the spirit as well as the letter of existing law."

An indication that the adulteration or misbranding of cosmetics was not taken too seriously in the past is the fact that, when the first national Food and Drugs Act was enacted in 1906, there was no attempt to include cosmetics in the protection offered to the consuming public. There were a number of incidents, however, some quite serious in nature, which soon revealed that protection against abuses in the distribution of cosmetics was necessary. For example, a cosmetic caused irreversible blindness to a few women who were particularly susceptible to one of its ingredients. A depilatory caused poisoning in some women, resulting in symptoms such as abdominal pain, nausea, loss of hair, and blindness. Thus, when the Federal Food, Drug, and Cosmetic Act was enacted in 1938 to supersede the 1906 Act, Congress set forth the specific circumstances under which a cosmetic shall be deemed to be adulterated or misbranded, and severe penalties were provided for those distributors or manufacturers who marketed products which could cause injury.

Drug Amendments of 1962

The statutory framework, under which the Food and Drug Administration functions, has changed radically during the quarter of a century since the passage of the Federal Food, Drug, and Cosmetic Act. It was the elixir sulfanilamide tragedy which caused the incorporation of the "new drugs" provisions in the Act, and it was the dramatic thalidomide episode which caused the immediate enactment of the Drug Amendments of 1962. Less dramatic with respect to public interest, but of substantial importance as to its impact upon industry, was the administrative construction of the law (sustained by the courts) that the "harmless per se" doctrine was applicable to coal-tar colors. This, in turn, provided the impetus for the 1960 Color Additive Amendments. These Amendments, extremely far-reaching in scope, could not be contested while they were pending in Congress because many colors, although not hazardous, would be outlawed.

In 1938, but for the provisions relating to new drugs and coal-tar color certification (which were the only original licensing provisions of the statute), fundamentally the same type of control was provided for foods, drugs, cosmetics and therapeutic devices. Implicit in the kind of regulation originally exercised was the assumption that manufacturers of foods, drugs, cosmetics and devices could generally be expected to adhere to the established statutory standards, and that those few who violated the law would be punished. On these bases,

which have been traditional and fundamental in our political and social system, no necessity existed for any extensive degree of direct governmental control in the nature of licensing. Through this past quarter century, however, for one reason or another (in some instances, perhaps for no valid reason at all), various changes have taken place which have altered the type of governmental regulation employed in the food and drug area. Today, a much greater degree of direct governmental control and licensing exists for such commodities than at the time of the passage of the Federal Food, Drug, and Cosmetic Act. As a result, a statutory imbalance has developed between the type of control exercised over foods and drugs and that which is exerted with respect to cosmetics.

In large measure this disparity now seems to constitute the main reason for the imposition of licensing controls on cosmetics. No compelling need has been shown at this time for more stringent governmental regulations in the cosmetic area, which would be the situation if an important gap existed in the coverage of the statute or if there were many serious injuries and if the incidence of reactions was high. Rather, the impetus for the greater degree of direct control appears to be predicated on the assumption that it is far simpler, from the government's viewpoint, to impose licensing controls. Of course, as we know, the task of completely satisfying the demands of the executive branch of the government is indeed a gargantuan one.

Cosmetic Injuries

There have been very few proven serious injuries from cosmetics since the passage of the 1938 Act. Instances involving some injury to some consumers, however, have occurred. For example, there was an outbreak of dermatitis as the result of the substitution by a manufacturer of synthetic resin for shellac in the manufacture of a hair lacquer very popular at the time. A number of years ago, two hair shampoos were marketed which, when inadvertently introduced into the eyes by users while shampooing their hair, produced opacity of the cornea which impaired vision for a period of time. There have been other instances of harm—from depilatories, deodorants, and other cosmetics. Nevertheless, there is no question but that, since 1938, the percentage of injuries caused by the many millions of cosmetics marketed has been small.

The fact that the 1938 Federal Food, Drug, and Cosmetic Act specifically provided that new drugs must be demonstrated to be safe

for their intended use before they are marketed, certainly did not prevent a number of unanticipated side effects, some of them quite serious, from new drugs which had obtained prior governmental clearance. This is not to say that regulation is not needed or that the new drug provisions of the statute do not serve an extremely useful purpose. The point is that it is impossible to have an absolute assurance that some few persons may not suffer some side effects occasioned by the use of a particular drug or cosmetic.

How Much Protection?

There is more than one public policy consideration to be borne in mind in connection with the passage of remedial, consumer-oriented legislation. Of course, by far the most important objective is to protect the consumer, who is particularly an amateur in the field of cosmetics. But do we wish to go so far as virtually to create a complete licensing system? Do we seek to impose requirements upon industry which do not give sufficient additional protection to the consumer to outweigh the complications, delay, and confusion which must ensue? Will this, together with the inevitable increase in costs, eventually be borne by those whom we are endeavoring to protect?

As I see it, the important task at this time is to weigh the various considerations which are involved in each determination as to whether to convey additional protection to the consumer. This depends in large part on one's theory of government. One can devise a statute which will vest such authority in the State, and require such testing and safeguards, that most old cosmetics will be regulated out of existence and very few new ones will appear. In addition, one can cause such an increase in the cost of cosmetics as to create a financial burden upon many millions of consumers. We can over-legislate and over-regulate so that the small businessman, who may be considered to be a bulwark of the economy, is driven from the marketplace.

A "New Cosmetic" Amendment

Thus, the answer to the question whether a new cosmetic amendment to the Federal Food, Drug, and Cosmetic Act should be enacted rests on one's philosophical approach to the place of government in our society. A "new cosmetic" amendment would in all probability give the consumer some greater protection than he has now. However, is this sufficient reason for exercising the vast control over all cos-

metic products that would result from its passage? Would the benefit from such legislation offset the risk which would follow?

Presumably, if one is of the view that the greatest possible protection must be extended to the public in all areas and in every way, the state must enter into the picture in an almost unlimited manner. For example, the Federal Trade Commission would examine all proposed advertising of cosmetics, and perhaps of all foods, devices and over-the-counter drugs, before they are employed. The Food and Drug Administration would scrutinize all proposed labeling of cosmetics, and presumably of all foods, drugs and devices, prior to use. The Federal Communications Commission would be authorized to determine what types of TV and radio programs and commercials should be permitted. Why stop at the categories of products covered by the Federal Food, Drug, and Cosmetic Act? Why not cover all products? In fact, why permit most advertising, the cost of which is ultimately borne by the consumer, to be employed, and why allow dozens of similar, and often wasteful, products to be marketed at all?

If our sole objective is to convey to the consumer the utmost possible protection, every food, drug, device and cosmetic company would have to be licensed by the government after demonstrating that it possessed the necessary capital, background, and personnel with the requisite qualifications and integrity. As a matter of fact, to round the picture out nicely, it would seem that the state might itself exclusively perform all pharmacological and clinical research.

If we do not wish to reach what I see as absurdities, then somewhere along the road of consumer protection we must pause and query whether the additional protection contemplated (and it presumably would constitute a further shield) may not be outweighed by the liabilities which necessarily go along with overly big government.

Existing Cosmetic Regulations

There are many who appear to forget that cosmetics are regulated under existing law. Thus, a cosmetic that is adulterated may be seized and condemned and multiple seizures may be made. A cosmetic which is misbranded because its labeling is false, or misleading in any particular, may likewise be seized and condemned. Those who introduce adulterated or misbranded cosmetics into interstate commerce may be enjoined. They, and their officers, agents, and em-

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ployees who had a responsible share in the furtherance of an illegal shipment, may be criminally prosecuted and found guilty regardless of motive or intent, and the possible punishment for each offending shipment is a fine of $1,000, or imprisonment for one year or both. A second offense, or a first offense with intent to defraud or mislead, is a felony. In addition, the definition of "drug" in the Act is so broad, encompassing articles "intended to affect the structure or any function of the body of man or other animals," that a number of courts have held that products which would traditionally have been called cosmetics were "drugs" and "new drugs," requiring preclearance by the Food and Drug Administration with respect to both safety and effectiveness. In addition, since 1960 the far-reaching Color Additive Amendments have been part of the law. If some minor changes in the Act are desirable, such as those regarding factory inspection and the making of reports (amendments which presumably should also be applicable to food and over-the-counter drugs) they could readily be contained in the Food and Drug Administration's recently proposed Food, Drug, and Cosmetic Amendments of 1974. In this connection, I may say parenthetically that it is gratifying to me to learn that the Food and Drug Administration is seeking legislation from Congress rather than relying on its own personal constitution which apparently permits it to legislate without troubling Congress.

Approach Further Regulation with Caution

I sometimes feel that we are fighting an irresistible force directed against an easily movable object. This is because of the seemingly inevitable trend in the food, drug, device and cosmetic area towards governmental licensing. Admittedly, this is occasioned, in considerable part, by actions taken by segments of the affected industries which should not have been taken. Yet the prevailing situation in the cosmetic industry, and the existing regulatory controls, do not require, at this time, the enactment of further legislation, despite the realization that consumer protection might be somewhat enhanced.

Another reason for being somewhat wary concerning further cosmetic legislation is the sad fact of life that the government frequently interprets new legislation in a manner never contemplated by Congress. For example, the original regulations issued under the Color Additive Amendments (ultimately held invalid in that respect by the courts) provided that finished products such as lipsticks and rouges were "color additives" because they were marketed for the purpose of

"coloring the human body." Yet, the legislative history of the Amendments did not reveal any congressional intent to classify finished cosmetics, as distinguished from cosmetic coloring ingredients, as color additives. It never occurred to the cosmetic industry, and I doubt that it occurred to the Food and Drug Administration, that the government would take the position it did in its regulations. Even Zeus, the supreme ruler of the gods, was not omnipotent or omniscient; he made mistakes. It is not startling to state that the government has been known to make mistakes—sometimes grievous ones. I hesitate to see the regulations expanded when I see no compelling necessity for it.

This is not to say that all consumer-oriented legislation should not be enacted because of the difficulties or errors which may ensue. For example, there is a definite need for an amendment to the Act creating additional governmental control in the field of medical devices. However, the considerations which call for such controls in that area are not now present in the field of cosmetics.

Further, in the case of cosmetics, for example, it is essential to provide, as one of the bills pending in Congress provides, that an application with respect to a cosmetic may not be approved "if the data before the Secretary show that its intended use or any use which can reasonably be anticipated would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act." It is not difficult to predict how this would be construed by the government.

Consumer Protection in Cosmetics

The Cosmetic, Toiletry and Fragrance Association, the trade association for the cosmetic industry, has done a very valuable job in leading the industry toward real consumer protection in the field of cosmetics. Thus, the CTFA has published Quality Assurance Guidelines, Microbiological Aspects of Quality Assurance, Microbiological Limit Guidelines for Cosmetics and Toiletries, Microbiological Quality Assurance Guidelines for the Management of Processed Water for the Manufacture of Cosmetics, Production and Control Documentation, Microbes, Sanitary Practices and You, and the CTFA Cosmetic Ingredient Dictionary, which is recognized by the Food and Drug Administration as the controlling compendium to be consulted in determining the name to be used in the labeling declaration of a cosmetic ingredient.

The Food and Drug Administration, pursuant to the authority it believes the Fair Packaging and Labeling Act conveyed to it, has directed the manufacturers of all cosmetics to list the ingredients on their labels. The Agency has stated that this requirement is needed to facilitate value comparison by consumers and to help those with known allergies to avoid products whose ingredients might cause reactions. Under the regulation, ingredients must be listed prominently and conspicuously in decreasing order of prevalence. With certain exceptions, all ingredients will be listed by standardized names, so that all manufacturers will be using the same name for the same ingredient. If a package is too small, a tag or card with the required ingredient information must be attached to the container.

Reporting Complaints

Further, a procedure has been established by the Food and Drug Administration for voluntary twice-a-year reporting of complaints received by manufacturers about their products. This information will be used to help the Agency determine any need for product reformulation or regulatory action. These data will also be utilized by it to help pinpoint products, product types, and ingredients that are causing injuries or allergenic reactions. In addition, the procedure calls for voluntary registration of cosmetic product establishments and filing of cosmetic product ingredient and cosmetic raw material composition statements.

In summary, it is my opinion that, in the past, additional cosmetic legislation was required. In my view, however, the strides made by both government and the cosmetic industry (an industry that has finally grown up), have so altered the situation that it would serve no useful purpose, from the viewpoint of the consumer, to enact cosmetic legislation at this time. The risk would far outweigh the benefit. **[The End]**

The Regulatory Gospel According to St. Peter[1]

By H. THOMAS AUSTERN

Mr. Austern Is With the Law Firm of Covington and Burling, Washington, D. C.

OUR SPEAKER is H. Thomas Austern who has practiced, taught, and voluminously written in Food and Drug law for more than four decades. He is therefore one of the deans of the Food and Drug Law Bar, and one of the original organizers of the Institute.

Indeed, many years ago Tom Austern strongly urged upon Charles Wesley Dunn that a brilliant and affable young student named Peter Hutt be awarded a Food and Drug Law Institute Fellowship for a year's study at New York University.

Recognition of Peter Hutt's talents and scholarship led to his association, and later to a partnership, in Covington and Burling where Mr. Austern had a little to do with his development.

Despite some current differences on legal and philosophical questions, they remain good friends.

Joshing and poking friendly fun among friends, and even among relatives, is commonplace. As Harry Truman once said: "If you can't take the heat, better stay out of the kitchen."

This evening we present Tom Austern in a new, and an ecclesiastical as well as ecumenical role, as he will recount for us "The Regulatory Gospel According to Saint Peter."

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[1] The following discussion, or perhaps sermon, was given by H. Thomas Austern of the District of Columbia Bar as a dinner address at Food Update XIII at Scottsdale, Arizona on April 24, 1974. To provide background for the reader, there is included the introduction of Mr. Austern by Mr. Daniel F. O'Keefe, Jr., President of the Food and Drug Law Institute.

The Sermon

Ladies and Gentlemen, or shall I not say Brothers and Sisters and Fellow Sinners:

Verily, I have a strange story to tell you. Last month, while idly strolling along the muddy banks of the Chesapeake and Ohio Canal, I stumbled over a metal box engraved with this strange inscription, "The True Word—21 C. F. R."

Inside that box was a small silver casket, with a principal display panel that recited, "Easily Opened Under the Freedom of Information Act." It contained a parchment scroll which I unrolled with avid curiosity and, in the fading afternoon sun, began to read what seemed to be a religious tract.

The style was vaguely familiar, nevertheless somewhat odd. Here's how it began:

"In the beginning was the Word, and the Word was in the Preamble.

"In these regulations the commandments are given, what thou shalt and thou shalt not do, to the end that law and consumer confidence may be one.

"And a huge temple, of basalt and white marble, was erected in Rockville from whence there poured an endless legal liturgy.

"And the scribers recorded it, and it was passed on to the people and to the afflicted industries throughout all the land, and it was called the Code.

"The legal scholars came and they parsed it, peering through the endless parchments of the *Federal Register*, and they told the people of its meaning and its practice, insofar as they could discern them.

"But many there were who thought them only legal soothsayers. And in the temple at Rockville, it was known that only St. Peter could truly divine the meaning of the Word.

"And often St. Peter came into the marketplace and beheld the sinners, as well as the saints, assembled together in Food Drug Law Institute (FDLI) convocation.

"And Peter, seeing the crowds, went up to the podium and taught them, saying

'Blessed are those who read proposals, for they shall neither sleep nor understand:

'Blessed are they who write comments, for they shall in turn inherit numbered paragraphs;

'Blessed doubly are those who object, for they shall receive summary judgment;

'Blessed are those who ask questions, for they shall surely be told; and

'Blessed are those who comply, for they shall surely be bankrupt.'

"Think not, further spake Peter, that I have come to abolish the laws of the prophets. I have come not to abolish them, but only to rewrite them.

"For truly, I say unto you, til heaven and earth pass away, not an iota, not a jot, shall be erased until it is fulfilled, in 6-point type, on the principal display panel.

"And Peter looked to the panoply of legal saints and declared their number too great, and some were soon decanonized and thoroughly debunked.

"No longer shall Due Process see us through our trials. A full hearing shall no longer be blessed.

"And the people were incensed, and they pled their case to the high legal priests of the land, but they were turned away and told that the old saints no longer reigned.

"And now the people sometimes meet, in remote desert places, secretly, to mourn their passing."

Well, Brothers and Sisters, at that point I stopped reading the scroll, with very blurred eyes, and some bewilderment. I leaned against a tree and pondered what I had found.

Long had I learned from Dick Hall that food and drug regulation had become somewhat of a religion, that it had its apostles and saints, along with its heretics and sinners, some of whom convened with Satan around Food and Drug Law Institute meetings, where as Brother Terry Hanold asked this morning, "In which house does Satan live?"

Perhaps in the calendar of saints you would put Harvey Wiley, Paul Dunbar, George Larick, James Goddard, Charlie Edwards, Mac Schmidt, and possibly Senators Magnuson, Moss, and Nelson, and Congressmen Fountain and Rogers.

Among the angels one could readily acknowledge the blazing glory of James Turner, Bob Choate, Michael Jaconson, and, of course, that archangel Ralph Nader.

And noticeable among the cherubim many had long admired Bess Meyerson, Virginia Knauer, Esther Peterson, Anita Johnson, and Ruth Desmond.

Discretion, of course, requires that I do not name any of those who have fallen from grace and gone elsewhere than to any regulatory heaven.

Yet, as far into the night I read further into that scroll, I trembled in fear about my old faith in law and order. At times I remembered the medieval monk who once wrote on the flyleaf of St. Augustine's "City of God," "I believe, oh Lord, but, alas, I do not understand."

Unfortunately, many of you here tonight have not had the advantage of either Jesuitical or Talmudic training, or possess the hieroglyphic skill of Joseph Smith. Others probably always played hooky from Sunday School.

So I shall not read or quote further from that mystic scroll. Instead, I will endeavor to summarize its inner meaning for each of you. Heed carefully what I tell you, else you may be legally damned forever.

To begin with, who was this Peter, who perhaps authored that sacred scroll, or as was his wont, certainly wrote that Preamble.

Of his early life, little is truly known. Like his namesake, he may originally have been called by the Hebrew name of Simion, or, in the Greek form, Simon. That was later translated into Petro, meaning the "Rock." Those who know of the Peter of whom I speak would readily agree how apt that name would be.

Now, it is also told, cryptically and only by implication, that our Peter was, as Mr. O'Keefe suggested, trained as a legal carpenter in some Institute course supported by the sinners. There is also an apocryphal story that, for a time at least, he had sharpened his tools in some den of legal devils called a law firm.

Somewhat later, Peter got the call and, like Elijah, ascended to his regulatory heaven where he constantly railed against the ancient beliefs that statutes meant what they said or that due process was sacrosanct.

Eventually his basic creed became that an objector should be less able to get a hearing than to pass through the eye of a needle.

You would be fascinated with all of Peter's revisions of ancient writings. However, it must suffice for me to offer only a few of his most important preachments.

One of his principal diatribes had to do with that heresy of Manna from Heaven. He commended the absence in it of any devilish chemical additives, but strongly felt that the children of Israel should have rejected any sustenance which did not contain adequate nutritional labeling. Indeed, he urged that Moses had sinned in leading them into the Sinai desert without honoring their right to know precisely what they would get to eat.

Some of you would probably have difficulty in understanding a related part of the scroll. For Peter granted that the unleavened bread, which the Hebrews call matzos, contained no artificial flavors. But he insisted that they were really matzos WONF, which I think meant for him that, on the back of the knapsacks, they should have been labeled Baked Wheaten Paste With Other Natural Flavors.

I suppose that if they had, the wandering emigrants from Egypt might have found oil in the Sinai desert, maybe even edible oil free of saturated fats.

Those matzos, Peter added, were indeed only Imitation Bread, a new and novel sunbaked product, but not nutritionally equivalent, and certainly not Lite Diet Matzos.

Brother McCormick, if you don't monkey with that metaphor, it will not monkey with you.

For Peter, administrative secrecy was always anathema. There is a long passage in that scroll that talks, in confused fashion, about Freedom of Information (FOI). According to that doctrine, the keys to the kingdom of heaven were to be given to the saintly James Turner and his followers who could demand FOI access with the calm assurance of a Christian holding four aces.

Yet it seemed that FOI did not always fulfill its holy objective. It became too full and choked up. Indeed, in that part of the regulatory heaven, so much paper soon built up that the angels and cherubims could not even wade through it.

Instead, the celestial custodians had to stuff it into boxes placed on high shelves out of reach, and those who remonstrated that they could not get at the holy word were invited to go down elsewhere.

Nevertheless, urged St. Peter, all papers and other records would have to be kept forever. His eternal notions on retention seemed to resemble the rules and regulations for the perpetual care of a cemetery.

Yet for Peter, Freedom of Information was only a one-way street. What went on inside his regulatory heaven could never be revealed to the unfaithful, except after they had been seized, convicted, roasted, and possibly converted.

Well, Brothers and Sisters, to jump to another part of that fascinating scroll, I wish I could explain his long catechism about something called the PDP.

It seems that when a devout consumer encounters a cylindrical container, Peter insisted that she must always walk around it only to the right. That seems to be what Joshua did at the walls of Jericho.

Label statements, saith Peter, have orbital positions like planets and electrons. If anything gets out of place, however slightly, the universe will fall.

Eventually I began to understand that PDP did not mean Principal Display Panel, but essentially Peter's Definite Positions.

Your next surprise would be to discover that in the regulatory heaven, as on earth, they have advisory committees. That in no way should be taken to mean that the doctrine of administrative infallibility is to be questioned.

St. Peter merely insists that an advisory committee should not be the stone which the builder would reject, but veritably the keystone of the arch on which he can stand high before a Congressional committee.

Yet, while saints have the advantage of living in heaven, they do not always agree. The scroll recounted some small troubles. For if Peter accepted what a saintly advisory committee offered, that irascible angel, Mr. Fountain, would insist that the advisory committee was biased and included industrial devils masquerading as angels. Yet, if Peter rejected what the advisory committee offered, he was always charged with disregarding objective, disinterested, and obviously sacred advice.

Thus it seemed that, while ordinarily what Peter wanted, Peter got, that was not always true in the heaven he made for himself. For in that regulatory heaven, there was also a trinity of judges—Bazelon, Leventhal, and Robinson—who vigorously objected to some of Peter's rulings. They admonished him at length because he made them, along with many others, "unnecessarily confused."

And in the organ tones of a legal Lord Jehovah, they told Peter that he could not covet an New Drug Application (NDA) without a hearing and that he could not change the regulatory catechism whilst the petitioner was praying.

Even a saint, thundered that higher authority, cannot deny a hearing or deafen his ears when one is vouched safe.

It is not wholly clear from the scroll how Peter repented. Yet he somehow contrived to send the petitioning purveyors of implanted beef to hell in some other fashion.

Regrettably, Brothers and Sisters, in the time available for this sermon, I cannot take you through the entire scroll.

For Peter, the dispensation that one should be forgiven because he knew not what had been done is heretical hearsay. He believes that everyone should be vigorously punished or put in the purgatory of a criminal trial, even though they have departed from the straight and narrow without knowing it, or because some employee unwittingly led them into the byway of an inadvertent violation.

Everybody, urges Peter, is his brother's keeper and should be jailed along with him. Even minor trespasses can never be forgiven.

You might again have difficultly following that harsh thesis. It might recall the preacher who dramatically admonished his congregation by asking that if there were any virgins in church, they should rise and stand before the congregation. And when a statuesque woman arose holding an infant in her arms, he demanded by what right she stood, and got the reply, "Reverend, if you think this little infant girl can stand by herself, you are mistaken."

For St. Peter, however, under his rugged rules about punishment, there is no presumption of innocence, save perhaps for those who humbly come to the altar and purge themselves by self-certification.

As I read that tough stance in that part of the scroll, I recalled Yeats' lament that:

"Everywhere

The ceremony of innocence is drowned;

The best lack all conviction while the worst

Are full of passionate intensity.

Surely some revelation is at hand."

Brothers and Sisters, it has been difficult indeed for a marked sinner to try fully to expound that regulatory gospel of St. Peter that I found along the canal. In my youthful innocence, I once thought I knew right from wrong, as perhaps did some of you.

Now I do not suggest that our St. Peter must be likened to Torquemada or that his Preamble was really written by some masked Spanish Inquisitor.

Those of us who had come to love Peter and had long admired his great talents, integrity, and dedication, and enjoyed his amiable friendship, came to believe that his tough catechism might perhaps be attributed to youth.

Some of you may recall that illuminating Sunday School quatrain:

"King David and King Solomon

Lived merry, merry lives

With many lovely ladies

And many, many wives.

But when old age o'er took them

With many, many qualms

King Solomon wrote the Proverbs

King David wrote the Psalms."

Even more, some of you sinners here may end up as I did by echoing Hamlet who observed:

"There are more things in heaven and earth,

Horatio,

Than are dreamed of in your philosophy"

and who finally concluded that:

"There is nothing either good or bad,

But thinking makes it so." **[The End]**

A Current Industry View of Nutritional Labeling

By ARTHUR W. HANSEN

Mr. Hansen Is the Director of Consumer and Environmental Protection, Del Monte Corporation.

IT HAS BEEN 405 DAYS since the Food and Drug Administration (FDA) published its Nutritional Labeling Order. Ever since that publication date, there have been innumerable seminars, workshops, articles, conferences, speeches, praises, criticisms, brochures, and, as you might expect, problems concerning this subject. It is also worth noting that there have been numerous nutrition labels appearing on grocery shelves—and from more than just one canner!

Audits of industry commitment to nutrition labeling have not been made. However, from a cursory evaluation, it is clear that manufacturers from various industry segments have adopted this new labeling format. Likewise, retail store chains are incorporating nutrition information more frequently. In addition to representing different industry segments, these nutritionally labeled products come from companies of different sizes. Clearly, you do not have to be big to voluntarily put this information on your labels.

If a food manufacturer or distributor has yet to take the plunge, what can he expect? Problems? Confusion? Criticism? Continued label changes? I would say "Yes" on all counts. I will give you some examples—most of them based on firsthand experiences.

First of all, if you are going to make labels you will need money. After you have the money problem solved, you will need to secure the appropriate lab facilities. If you cannot afford to carry out your own analytical analyses, these services are available from many outside sources. Again, money will be necessary.

As nutrition data were being developed, it was assumed that one could expect variations attributable to different growing areas, varieties, harvesting practices, processing techniques, etc. To account for these differences, additional samples would need to be analyzed. For example, let us consider what was required for peas.

Consider the research design needed for just *one variety* of the many different pea varieties we grow. For this variety, there are three major growing areas, encompassing 11 pea canneries. Also, shelf life had to be considered.

Similar designs were developed for our other products. Fortunately, most were not as complex as our peas. Obviously, the fewer variables, the smaller the sample size. This is the reason why it is not too difficult for the smaller processor to develop nutrition data for his product line.

Quality Control Procedures

Some variables can be controlled, and some cannot. Those factors that cannot be controlled must be dealt with by using very conservative numbers on the labels. Those within our ability to control require the *application of the best possible quality control* procedures consistent with the economics of the product. Let me give some examples:

1. Products of two or more ingredients, such as fruits for salad, must be carefully controlled as to the proportion of ingredients.

2. The quantity of oil to be added to canned tuna can significantly affect the caloric value.

3. The Vitamin C content of fruit juices is influenced by the production techniques.

For example: Continued heating when exposed to air will cause a significant loss of Vitamin C.

4. Some vitamins, such as B, are heat sensitive; therefore, excess processing could cause significant changes.

5. Variations in solids to liquid ratio will affect the nutritional composition.

6. The use of new varieties may necessitate changes in the declared nutrient content.

We followed these initial research projects with an auditing program. Herein lie other problems. When variations are noted in the

audit results, what does one do? You must decide whether the variation would cause the product to be out of compliance. Does the variation reflect an error in the initial data or is it a non-recurring incident peculiar to that particular growing year or area?

Is the difference significant nutritionally to the consumer's interest? In other words, we must not get carried away by numbers alone.

How important is it to make a minor adjustment—one that has no bearing on compliance—in your labels? These are some of the problems that must be resolved.

Fortunately, we have had relatively few variations arise. Some of our most complicated problems have involved geographical location. We found that less than 10% of our production of one product had one of the vitamins present in a quantity significantly lower than in the other 90% which was produced in different regions. It was therefore necessary to grossly understate the majority of our labels for that vitamin.

Serving Sizes

Still another problem demonstrates the kind of confusion that can arise. I am speaking of serving sizes. As most of you know, FDA's regulations require the label information to be based on a given serving, as defined in the regulations.

Most food industry segments concur that uniform serving sizes are essential for nutrition labeling. However, such uniformity has not completely prevailed.

We see *solid* foods having ½-, ¾-, and 1-cup servings. Beverages have been considered on various measures also. It is not to be expected that the tuna processor, corn canner, berry freezer and the juice packer should all use the same common serving size. But it is undesirable for different serving sizes to appear within one industry segment. Such practice simply invites additional regulation.

Agreeing on a reasonably uniform serving-by-volume is just the first step. Next comes a consensus on the weight of the volume being measured. In working with other canners on their nutritional results, the differences invariably are attributable to the different weight for the volume being measured. This is understandable. But such situations cannot be ignored.

I submit that the foregoing situations are, in part, symptomatic of a more critical problem that should not continue unchecked. I am referring to the term, "*serving.*" This word is understood by common --and now legal—definition to mean what one normally consumes. That would be all right if we all ate the same size serving.

In order to eliminate the confusing connotation in the word "serving," the word "portion" still appears to be the best term. The FDA does permit the use of "portion" but only under limited circumstances. Basing the nutrition information without the limitations currently imposed by the FDA on a given "portion" simply would tell the consumer some facts about that quantity of the food. We think, for many foods, that *one cup* is a practical quantity for the consumer to work with—regardless of whether or not it is a "*serving.*"

In many respects, confusion still prevails as to whether nutritional labeling will be useful. This debate may continue for some time. On occasion, a shopper may stop and study the nutritional labeling. But this probably will not happen that often. I think we can agree that the shopper will not weigh servings on an analytical balance before meal preparation. No one expects that.

Conceding the foregoing, what is the point of these label changes that many are undertaking? Well, let us agree that this information was developed and printed in response to a demand for it. O.K., then what? The consumer has it and if she cannot really use it in the store and she hasn't time at home, what is she going to do with it?

Nutrition Education

I do not think anyone expected nutrition labeling to "make it" on its own. Strong agreement existed that nutrition labeling was just one facet of nutrition education. Consumers do need a crash course in how to use nutrition labeling. Just one example—our Manager of Consumer Services was discussing the new labeling with a group of college-educated homemakers. After looking over a sample label, one asked why the percentage did not add up to 100%!

Another question frequently asked of us is, "Are those nutrients on your labels the only ones that are important?" Certainly not. This is why we added the phrase, "For good nutrition, eat a variety of foods." Hopefully, we will never be asked to include all the 40-to-50 nutrients that are essential to life.

There is a high probability that if people meet the U. S. Recommended Daily Allowance (RDA) for those nutrients specifically listed, the other nutrients will be satisfactorily supplied in one's diet. I think the phrase, "For good nutrition, eat a variety of foods" is the most valuable information on our labels.

The FDA and United States Department of Agriculture (USDA) do have nutrition education materials in the works. Whereas the primary responsibility for developing such consumer knowledge on this subject does not lie with the food industry, the industry has taken steps to aid the consumer with nutrition education material. Even though these materials are available from our Company, other companies have similar resources.

I have noted with interest a marked increase in the number of food advertisements that now include some kind of nutrition message. Such ads do not predominate, but the frequency is up.

Nutrition awareness has been stimulated and is growing. If nutrition education—including nutrition labeling—is properly brought into our primary and secondary schools, those homemakers who do turn the can around to read the information panel will at least understand and have some appreciation for what they are reading.

Cost

How about the cost? Is it really worth all that money? "It's inflationary!" That response is another example of the confusion that often surfaces. I cannot speak for any other company, and please bear with me while I mention briefly another Del Monte example. We developed estimates that the cost for developing the data and changing the plates (over a two-year period), was about 1-1½ cents per 100 cans. Our auditing costs approximate 1 cent per 2,000 cans. I realize that every little one-cent charge can add up to a big bill. But these costs are not all that inflationary—particularly compared to other labeling cost increases that the food industry has been facing; for example: In the past 12 months, label paper has increased 18-28%, pigments, varnish and other materials have gone up 100%. Fiber boxes are now 30% more than they were seven months ago.

Well, enough of the overview. Let us peer into the crystal ball for a while. Certainly, there must be something besides FDA's nutrition labeling regulations. There sure is!

We can choose from the USDA's nutrition regulations. They would follow FDA's regulations, but also would require that those which must be cooked prior to eating have a second column showing "as cooked" data. Also, an expensive audit program would be required.

If you do not like that choice, how about the FTC's nutrition advertising guidelines? From what I have seen, these proposed advertising procedures are not apt to be embraced too dearly. It is vitally important, whatever regulations are finally adopted by the FTC, that these requirements not be so restrictive as to prevent nutrition education via advertising. I hope we can make the FTC understand this.

Once you have all of your nutrition labeling matters resolved, do not think you can sit back and give a sigh of relief. Blue skies do not prevail yet in the horizon. Drained weight labeling, open dating, percentage ingredient declarations, metric equivalents, grade labeling, are some of the potential problems which must be resolved in the future. Let us all (consumers, government, and industry) be sure we do not push for something which does not provide real benefit to consumers commensurate with cost, label space, etc.

All of these foregoing labeling matters would compete for our extremely limited label space. *Plus*, the food industry is deeply involved in the addition of the universal product code (UPC) symbol on labels. This UPC symbol will streamline the retail grocery business, but it also takes up considerable label space. (As an aside, it is estimated that 50% of all supermarket products—except meats and fresh produce—will have this symbol by the end of 1974. This represents 84% of all supermarket sales—again not counting meat and produce.)

Conclusion

I have described some of the problems and requirements to be dealt with if you nutritionally label food products. In summary, I would like to make some observations based upon a review of the path we followed to develop nutritional labels for our products and how we view nutritional labeling today.

Nutritional labeling does present many technical problems but none which cannot be resolved by good analytical and statistical procedure, and the real key—a thorough and effective quality control program.

The initial nutritional labeling cost is quite high, but the subsequent cost of maintaining an accurate nutritional labeling program is fairly low. Dr. Virgil Wodicka described it perfectly when he said, "The initiation fee to join the nutritional labeling club is high, but the annual dues are low."

Most important of all—is nutritional labeling beneficial to the consumer? We believe consumers do consider that nutritional labeling is highly desirable and useful.

Nutritional labeling is in itself a form of nutrition education, and one which must be augmented by other forms of nutrition education for its full potential to be achieved. We view nutrition labeling as one very significant step toward greater consumer awareness and knowledge of nutrition and, as such, the most important new development in food labeling to date.

We have been asked if we had to do it over again, would Del Monte make the same decision to embark on nutritional labeling—without hesitation the answer is an emphatic YES! **[The End]**

FDA ISSUES FOOD LABELING ORDERS

In its fourth major action to regulate food labeling and nutritional quality, the Food and Drug Administration has issued four final orders and has withdrawn two propsals previously issued.

The final actions taken by the FDA at the same time set standards of identity for table syrups; establish procedures for use of U. S. RDAs for nutritional labeling of infant, baby, and junior-type foods; permit the optional addition of vitamin C to tomato juice; and confirm the effective date of rules calling for the use of "International Units" instead of "U. S. P. Units" for vitamins A and D. A proposal concerning the labeling of fats and oils has been withdrawn and replaced by provisions of one of the newly issued proposals and a proposal to establish a standard of identity for textured protein products has also been withdrawn.

Alexander M. Schmidt, M.D., Commissioner of Food and Drugs, said that these latest actions represent the FDA's continuing response to the "challenge" imposed upon it by the White House Conference on Nutrition. The Commissioner said that it has become apparent that better guidelines for the addition of nutrients to foods are needed as a result of current development of new sources of protein, new kinds of manufactured food, and new developments in food technology.

CCH Food Drug Cosmetic Law Reports

Nutritional Labeling Revisited—Regulatory Considerations

By J. LYLE LITTLEFIELD

Mr. Littlefield Is the Government Relations Manager of the Gerber Products Company.

I AM HONORED TO BE INVITED to participate in Food Update XIII. When I was first approached by Dr. Hopper to discuss this subject, I was convinced he remembered me most from my regulatory days in Michigan. In fact, he was reminded I had been away from actual enforcement work for about five years. At any rate, last December he persuaded me to become involved and here I am—for better or for worse, and delighted to be here.

The whole gamut of nutritional labeling and its regulatory considerations is rather mind boggling. It was on March 30, 1972, when history was again made by the Food and Drug Administration (FDA), when the initial regulations on nutritional labeling were published in the *Federal Register*.

Multitudes of comments were filed. The record indicates a total of 3,140 comments were filed with the bulk of these coming from individual consumers. I suspect that this is, by far, the largest number of comments received by FDA on any proposal.

Nutritional labeling seems to be an outgrowth of the White House Conference on Nutrition in December of 1969. Label declarations of nutritive values were one of the most publicized of the numerous recommendations to emerge from that conference.

Out of this real or fancied demand there came nutritional labeling. The next question seems to be, what form such labeling would take. It is rather logical to assume that no one—save the drafters of the proposal—anticipated such a complex, costly, and even burdensome system.

I shall not delve into details—I doubt there is anyone here who is not deeply familiar with what has been published and continues to be published with near regularity. To say confusion has been and is currently reigning would be a gross understatement.

Role of State Officials in Drafting the Regulations

In my visits with people from the state regulatory agencies it is difficult to find much enthusiasm for the whole program. There could be several reasons for this lack of enthusiasm. One could be that they do not understand the regulations. Should this be so, the dilemma is shared with an industry which is laboring to comply.

One state official summed it up rather pointedly at the Association of Food and Drug Officials of the United States (AFDOUS) last summer during a FDA discussion of nutritional labeling when he volunteered: "The whole mess should be dumped."

As I have looked at the hundreds of pages from the *Federal Register*, it seems clear that there was not a great deal of input from state officials. There were a few attempts, but generally the effort, while recognized, fell on deaf ears.

I believe there are other reasons state officials may not be thrilled with all this. That is, in general, the regulatory considerations would appear to rest firmly with FDA—leaving most, if not all, states out of the enforcement program when there is one. Generally, states lack the expertise for the detailed sampling and analysis which will be required. Further, there are costs involved. Personnel and laboratory equipment for this work are not inexpensive. Thus, the major enforcement thrust would be at the federal level.

Just recently I noted that some writer expounded on the very low cost of such a program. This is "industry cost" being discussed. Up to this time I surely could not have agreed that it cost practically nothing as the writer suggested. Art work, label design, and printing are not inexpensive. So the cost/benefit ratio comes into play—or at least it should.

Late last year a survey was conducted which indicated only 37% of the shoppers utilize product information such as nutritional labeling, open dating, and unit pricing. This is a higher figure than before. Interestingly, though, 80% of the shoppers said they were familiar with such label information; so ignorance should not be considered as a reason for lack of use.[1] To improve on this 80%

[1] Progressive Grocer, December 1973.

figure, some sort of consumer educational program should be undertaken. Be that as it may, there remains the common argument: "so what if the consumer does not use the information—they have the right to know—and it is there if they want it."

This reminds me of a report, a couple of months ago, from a vegetable canner who elected to nutritionally label peas or green beans. The processor received only one comment from a consumer. It went something like this: "I've been using your product for years and always liked it—why in the world did you ruin it by putting all of those additives in it?"

Complexity of Regulatory Considerations

Regulatory considerations are complex. There is a great deal we will not know until the industry and the regulatory agency have some experience. Surely, any regulatory approach must have the application of a "rule of reason." For enforcement purposes we are dealing with the Class I and Class II nutrients.

In Class I nutrients the composite must be at least equal to the label declaration. No mention has been made of any tolerance—even for analytical error. The Class II nutrients, by analysis, must be equal to 80% of the value declared. This recognizes, at least to a degree, the variations of naturally occurring nutrients. We will learn by experience what tolerance might be applied. There could well be consideration of broadening the regulatory limits for Class II nutrients to include a level of $\pm \frac{1}{3}$ which most nutritionists agree would not cause serious problems from a dietary management standpoint.

Interestingly, one of the early criticisms of the proposal concerned the several triggering mechanisms. For example, if calories per serving were given, this information would require the complete nutritional labeling format. Yet, the product might be just a condiment to be used on other foods. *Calories* is an area of much interest.

At any rate, a proposal was recently issued which is designed to correct this deficiency—at least in part. I do not believe it goes far enough. I am not certain, for example, that the fortification of a food with a single vitamin (such as vitamin C) should necessitate an entire nutritional information panel when the rest of the nutrients might be at the 2% Recommended Dietary Allowance (RDA) levels or none at all.

It seems to me, too, that there is a possibility of a "horsepower race" in the fortification of some nutrients. Only time will tell. Furthermore, it is questionable just how much attention may be given to the label by the consumer.

It is hoped the regulatory agencies, either federal or state, will proceed with this program with a degree of reasonableness. To do otherwise would only compound the problem, and add to the cost.

At this time, I can comment from some personal experience on regulatory considerations. Probably all, or nearly all, in the audience read the Food Chemical News. If so, you might be aware that Gerber came out with a "fortified peanut spread with a touch of honey." We are in test market in one city. After three months deliberation, FDA advised us:

1. There could be such a product with less than 90% peanuts if we declare percent of peanuts on main display panel.

2. We must also declare percent of honey.

3. If the product had less protein than peanut butter, it is an "imitation."

4. Drawing on one of the regulations that says "every food is not a proper vehicle for fortification," they have indicated our peanut spread is such a food. Further, we cannot carry information for both children under 4 and adults on the same label.

Probably these are regulatory considerations we had not contemplated. At about the time we were notified by FDA, a similar product (without fortification) was to be test marketed by another firm.

None of this is completely resolved at this time. In all the nutritional briefings there was every indication that industry could use dual nutritional declarations. Now it is apparently a "no-no." So, if this is so, we cannot provide adults with nutritional information on the same label that carries "children under 4" information.

Nutritional Labeling of Meat and Poultry

In commenting further on regulatory consideration, I would be remiss if I did not comment on the recent package of nutritional labeling proposals from the United States Department of Agriculture (USDA) on meat and poultry. This program is far from finalized, but some processors are using nutritional labeling.

This program is being touted as following closely the FDA regulations. This is so, as far as the format goes, but similarity ends there. USDA has included a control procedure in the regulation which must be met before going to nutritional labeling. This sets a procedure in cement and I do not believe it belongs in a regulation. There is no flexibility provided for.

It seems to me that the USDA proposal is really designed to discourage nutritional labeling. We have indicated this in our formal comments. The control procedures place such a heavy burden on multi-product companies that they might desire to forego nutritional labeling. Yet, the same triggering devices are established that are in the FDA regulations.

As this proposal now stands, the analytical work alone, under the sampling program, would cost Gerber about ½ million each year. Very frankly, we are not encouraged about this approach to nutritional labeling. Yet, if we say anything about nutrition anyplace, we are required to use a nutritional label.

There is further regulatory consideration. USDA is likely to do much of their own analytical work, leaving the states completely out by using the preemption provision of the Wholesome Meat Act. On the other hand, many states enjoy a fund-sharing program on inspection, which could anticipate states being more deeply involved.

While the USDA program may fall under the preemption section of the Wholesome Meat Act, as I mentioned, so might there be preemption of states by FDA. This is the feeling I believe exists among state officials in many areas of regulation today. There have been so many discussions of federal preemption and the need for uniformity, that I will not speak much further about this point.

I really believe state officials recognize the need for uniformity, however, what they do not want to recognize is the need for preemption. If preemption is not seen as necessary then we seriously need compatibility of state and federal requirements.

We must recognize that the lack of uniformity is not always the fault of the state official. Many legislative leaders do their own thing and the state program director is hard put to oppose such nonuniform legislative proposals.

If there was ever a time we needed compatible laws and regulations, it is now. For a horrible example, analyze the open-dating provisions which are currently in use, as well as those under consideration.

Let us hope we can have compatibility for nutritional labeling. If we do not have it, the regulatory considerations will be monumental.

I have only touched briefly on many of the regulatory considerations. Nothing has been said here about special dietary foods—or the occasions when a food might become a drug—but I am confident most have studied the regulations in depth. **[The End]**

The New FDA Hearing Regulations— An Analysis

By DANIEL MARCUS

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FDA'S NEW HEARING REGULATIONS, published in the *Federal Register* of March 13,[1] represent a watershed—but perhaps not the final word—in a five-year running battle between the Agency and the pharmaceutical industry—over whether and under what circumstances a manufacturer is entitled to a hearing before his drug product is removed from the market for lack of substantial evidence of effectiveness.

It seems doubtful that the new regulations reflect or augur any change in the Agency's well-known aversion to the holding of hearings. But they do recognize, in two significant respects, that the process of deciding whether a hearing is necessary must be more careful and fair than it has sometimes been in the past. *First*, and most important, the Food and Drug Administration (FDA) has recognized a legal requirement for the adequacy of notice to the manufacturer: Only a "specific" notice can serve as a basis for summary judgment. A manufacturer asked to respond to a "general" notice of opportunity for hearing must be given a second chance, by way of an opportunity to respond to the Agency's proposed final order, before summary judgment can be awarded. (The hitch comes in defining what constitutes a specific notice.) *Second*, FDA has made a nod in the direction of those who have argued that it is unfair for the Commissioner to be in the position of awarding summary judgment to himself. The new regulations require a separation of functions, removing the

[1] 39 *Fed. Reg.* 9750.

Commissioner's office from the prosecutorial decision to seek withdrawal of a New Drug Application (NDA), and forbidding those in the Bureau of Drugs, who have made that decision, from advising the Commissioner on whether summary judgment should be awarded.

Events Leading to Promulgation of New Regulations

In understanding the new regulations, it is useful to review briefly the chain of events leading to their promulgation. It is difficult to recall that, only a few short years ago, many members of the industry assumed that the words "opportunity for a hearing" in Section 505 of the statute embodied a more or less absolute right to a hearing at the option of the manufacturer before an NDA was withdrawn. But this was before FDA got around to implementing the 1962 Drug Amendments on the effectiveness of those products approved for marketing between 1938 and 1962. That process began in earnest only in 1968 and 1969, when the Agency began processing the first of the National Academy of Sciences-National Research Council (NAS-NRC) reports on the effectiveness of 1938-1962 products. The Agency, which had staggered through the peanut butter hearing and was bogged down painfully in the longest administrative hearing of them all—the infamous vitamin-mineral hearing—was understandably appalled at the thought of having to hold hearings on hundreds of NDA withdrawal proceedings, or antibiotic monograph repeal proceedings growing out of the NAS-NRC review. It directed its energies—and has continued to do so to this day—not to exploring ways of streamlining and expediting hearings, but to avoiding hearings at all costs.

FDA's Position on the Removal of Certain Antibiotics

FDA focused initially on several antibiotic combinations, and advanced a rather extreme position: that because of public health considerations (albeit ones short of an imminent hazard to the public health) certain antibiotic monographs should be repealed forthwith, before even deciding whether the affected manufacturers were entitled to a hearing. This approach, to remove from the market first and hold hearings later, was firmly rebuffed by two district courts: *Upjohn Co. v. Finch*, 303 F. Supp. 241 (W. D. Mich. 1969); *American Home Products Corp. v. Finch*, 303 F. Supp. 448 (D. Del. 1969). While not ruling on the legal sufficiency of the companies' objections, both courts indicated they were impressed with the submissions and hinted they were sufficient to justify a hearing.

These setbacks sent former FDA general counsel Goodrich to the drawing boards to come up with two related sets of regulations: one spelling out for the first time the criteria for adequate and well-controlled clinical investigations, and the other requiring a demonstration that those criteria were met as a condition for obtaining a hearing. These regulations were published in September of 1969,[2] concurrently with the Commissioner's award of summary judgment to himself in the "Panalba" case.[3]

Violation of Administrative Procedure Act

In a suit brought by the Pharmaceutical Manufacturers Association (PMA), the September 1969 regulations were set aside on the ground that by issuing them without notice and opportunity for comment by interested parties, the Commissioner had violated the Administrative Procedure Act: *PMA v. Finch*, 307 F. Supp. 858 (D. Del. 1970).

In May of 1970, FDA repromulgated both sets of regulations after receiving comments. It made some changes in the regulations, discussing adequate and well-controlled tests which effectively blunted PMA's objections to the original 1969 regulations. However, an ambiguous response by the Commissioner to a series of questions about the new procedural regulations left PMA in doubt as to the *bona fides* of the new summary judgment procedure. A second lawsuit was brought, claiming that the new regulations did not in fact establish a genuine summary judgment procedure, but still permitted the Commissioner to resolve disputed issues of fact as a basis for denying a hearing.

Summary Judgment Regulations Upheld

In *PMA v. Richardson*, 318 F. Supp. 301 (D. Del. 1970), the district court upheld the 1970 summary judgment regulations. Judge Latchum ruled that FDA's regulations did establish a genuine summary judgment procedure, and that it would be time enough for the courts to step in if the Agency misapplied those regulations in practice. He was, no doubt, reassured by statements during the oral argument by Mr. Goodrich that, when genuine disputes existed as to whether a particular study complied with the new regulations, a hearing would be held.

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[2] 34 *Fed. Reg.* 14596.

[3] 34 *Fed. Reg.* 14598. See *Upjohn Co. v. Finch*, 422 F. 2d 944 (6th Cir. 1970).

In practice, FDA applied the regulations so as to deny a hearing in every case. It was generally upheld by the courts[4] until it ran into the Fourth Circuit in the *Hynson, Westcott and Dunning* case.[5] One may ruefully recall that it was FDA's loss in the Fourth Circuit in the *Hynson* case that triggered the chain of events that led to no less than five cases being brought before the Supreme Court for a series of decisions which, in one day last year, wiped out many of the industry's long-cherished legal assumptions.[6]

The Question of a Right to Hearing

Indeed, the only area in which the industry salvaged anything from the Supreme Court's decisions was on the question of right to a hearing. Justice Douglas' opinion for the Court in the *Hynson* case concerning the hearing issue, read until the very end as if it were going right down the line with the Agency: the regulations defining adequate and well-controlled investigations were valid; FDA's 1970 hearing regulations constituted a valid summary judgment procedure placing the burden on the manufacturer to come forward with evidence showing that he was entitled to a hearing; and hearings were unnecessary when it conclusively appeared from the pleadings that the manufacturer lacked the necessary evidence. Then, in an abrupt shift, Justice Douglas announced that there was a division of opinion in the Court as to the adequacy of Hynson's submission requesting a hearing; that a majority of the Court believed the submission to be adequate; and that accordingly the Fourth Circuit was affirmed and FDA directed to hold a hearing. In a strange way, the *Hynson* case represented a real victory for the industry in this area. For, while the Court upheld FDA's summary judgment approach in broad language, it effectively punctured the notion that hearings would never have to be held.

Hearings for NDA's Withdrawals

Moreover, with the Supreme Court's resolution of the other issues before it last spring, the determination whether a hearing must be held on an NDA withdrawal becomes more critical than ever. For FDA's decision on withdrawal of the NDA resolves—subject to

[4] *Upjohn Co. v. Finch*, 422 F. 2d 944 (6th Cir. 1970); *Pfizer, Inc. v. Richardson*, 434 F. 2d 536 (2d Cir. 1970); *CIBA-Geigy Corp. v. Richardson*, 446 F. 2d 466 (2d Cir. 1971). See also *American Cyanamid Co. v. Richardson*, 456 F. 2d 509 (1st Cir. 1971); *Bristol Laboratories v. Richardson*, 456 F. 2d 563 (1st Cir. 1971).

[5] 461 F. 2d 215 (4th Cir. 1972).

[6] *Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U. S. 609 (1973).

appeal—not only the question of whether a particular drug is entitled to continued new drug approval under the statute, but also whether it and all related drugs are generally recognized as safe and effective or "grandfathered" and therefore legally marketable outside the new drug provisions of the statute.

Aggressive Use of Summary Judgment Procedures

In the year since the Supreme Court decisions were handed down, it has become apparent that FDA is still committed to the aggressive use of the summary judgment procedures, which were upheld in *Hynson*, as a vehicle for denying hearings in most, if not all, cases. When one reviews the record of the last five years, the energies expended by the Agency and its legal staff in avoiding hearings in its implementation of the NAS-NRC efficacy review are truly prodigious. With benefit of hindsight, one may question whether implementation of the review might have been better served by holding hearings in a number of the early contested cases, and demonstrating FDA's ability to conduct efficient but fair hearings in order to resolve disputed factual issues expeditiously. It is inconceivable to me that there are no cases having genuine disputed factual issues which—under the statute and under our fundamental concept of fairness—should be resolved in an impartial forum. A forum in which the manufacturer has an adequate opportunity to set forth his side of the controversy and explore defects in FDA's position.

The main issue on which controversy has focused since the Supreme Court's decision in *Hynson*, is the important issue of whether the Agency's summary judgment procedures really provide the manufacturer with a meaningful opportunity to know and to meet the Agency's objections to the company's evidence. You may recall that prior to the Supreme Court decision (in a case separate from those before the Court), the D.C. Circuit had ruled, in reviewing FDA's withdrawal of its approval of NDA's for USV's bioflavonoid drugs, that the Agency had the burden of proof on summary judgment, and that its initial notice of opportunity for hearing to the manufacturer must set forth a *prima facie* case. That is, the manufacturer must set forth facts which, if true, would justify the award of summary judgment to the Agency.[7] The *USV* case had had an unusual procedural history, and the Agency chose not to seek Supreme Court review of the Court's decision.

[7] *USV Pharmaceutical Corp. v. Secretary of HEW*, 466 F. 2d 455 (D.C. Cir. 1972).

Placing Burden of Evidence on Manufacturer

There is little doubt that some of Judge Robb's broad language in the *USV* case, as to the Agency's burden of proof on summary judgment, was undercut by the Supreme Court's *Hynson* decision, which clearly approved placing the burden on the manufacturer to come forward with evidence establishing the existence of material factual disputes. But the Supreme Court did not address itself specifically either to the Agency's burden to present initially a *prima facie* case or to the adequacy of the opportunity of a manufacturer to respond to the Agency's objections to his studies.

Genuine Opportunity to Respond

New life, it appeared, was blown into the old *USV* decision and the principle that a manufacturer must have a genuine opportunity to respond to the Agency, by the D. C. Circuit's decision this past January in the *Hess & Clark* and *Chemetron* cases.[8] The Court reversed FDA's action in withdrawing approval of new animal drug applications for diethylstilbestrol (DES) without a hearing. The issue in the DES cases was safety, not effectiveness. But the principles of administrative law announced by Judge Leventhal in the *Hess & Clark* case, and apparently concurred in by no less than four other judges,[9] were ones that transcended the particular substantive issue involved. Summary judgment procedures were appropriate, the court held, as was the placing of the burden on the manufacturer to demonstrate the existence of disputed facts. But the notice given by FDA to a manufacturer, Judge Leventhal wrote, "must contain enough information to provide the respondent a genuine opportunity to identify material issues of fact."[10] And later in his opinion, Judge Leventhal stated:

"If the Commissioner of FDA is relying on his notice as a device for invoking a summary judgment procedure that avoids the statute's general requirement of a hearing, he must include in such notice reference to the 'facts' that he deems to be established in order that there may be meaningful opportunity to controvert the alleged facts and present a material issue for hearing. This includes, at a minimum, presentation of the prima facie case required in *USV* as a predicate for withholding the hearing required in general for revocation of an approved application."[11]

The original *USV* holding may, Judge Leventhal noted, have to be refined somewhat in the light of the Supreme Court's *Hynson*

[8] *Hess & Clark v. FDA*, — F. 2d — (D. C. Cir. No. 73-1581), decided Jan. 24, 1974; *Chemetron Corp. v. HEW*, — F. 2d — (D. C. Cir. No. 72-1864), decided Jan. 24, 1974.

[9] Bazelon and Robinson (in *Hess & Clark*) and McGowan and Tamm (in *Chemetron*).

[10] *Hess & Clark*, *supra*, slip op. at 13.

[11] *Id.* at 14-15.

decision. But *Hynson,* the court emphasized, did not "overturn *USV's* requirement that the Agency make some showing as a predicate for summary adjudication."[12] Then Judge Leventhal somewhat cryptically added—in an apparent effort to reconcile *Hynson* with his own decision—that the Supreme Court in *Hynson* had

> "rather found that such a showing and predicate was supplied by particularized regulations setting forth precisely what the manufacturer was required to supply and by findings that the study adduced was conclusively deficient."[13]

Of course, in *Hynson* the findings—setting forth for the first time FDA's analysis of the deficiencies in the manufacturer's studies—had come at a stage where there was no further opportunity for the manufacturer to respond. And, as we have noted, the Supreme Court, in *Hynson,* simply had not focused on the question of adequacy of notice and opportunity to respond.

The *Hess & Clark* decision came down shortly before comments on the proposed revisions to FDA's summary judgment regulations were due. The opinion was emphasized in comments filed by PMA and others, who argued that *Hess & Clark* showed that the old *USV* principles were still valid, and that the Agency must set forth its full factual case, including analysis of studies of which it is aware, in its notice of opportunity for hearing.

Final Revised Summary Judgment Regulations

The final revised summary judgment regulations conceded the principle that only a specific notice of opportunity for hearing can serve as a basis for proceeding to summary judgment. When a general notice of the type employed in the DES cases is used, the Agency conceded, it cannot advance directly to summary judgment. It can still, under the new regulations, require the manufacturer to come forward with his factual showing. But before proceeding to summary judgment after that showing by the manufacturer, the Agency must first provide the manufacturer with a detailed factual analysis of his showing and give him a further opportunity to rebut the Agency's objections to the material on which he relies. This "second chance" for the manufacturer to show the existence of material factual issues requiring a hearing comes under the new regulations in the form of a proposed final order, which is served by mail on the manufacturer (and apparently not published in the *Federal Register*), with an additional sixty-day period for the manufacturer to respond.

[12] *Id.* at 16. [13] *Ibid.*

This two-stage summary judgment procedure—with a general notice of opportunity for hearing followed by a proposed final order analyzing the manufacturer's submission in detail—avoids placing the burden on FDA to produce a detailed factual notice in the first instance in all cases, while still arguably meeting the spirit of the *Hess & Clark* decision. FDA's desire to avoid this initial burden is understandable, since in many cases FDA's proposed withdrawal of approval will not be contested by the manufacturer. The procedure does place an arguably unreasonable burden on the manufacturer, requiring him to marshal his factual materials at a time when he may be unaware of precisely what it is that FDA thinks is the problem. But it does ensure him, through the proposed final order procedure, an opportunity to meet the Agency's objections.

FDA's Typical Notice of Opportunity

The hitch, of course, comes in the fact that FDA considers its typical notice of opportunity for hearing, in the implementation of the NAS-NRC review, to be a *specific* rather than a *general* notice, triggering its summary judgment procedures and dispensing with the need for a proposed final order. Relying on the sentence from Judge Leventhal's *Hess & Clark* opinion quoted above, FDA takes the position that its efficacy review notices—by incorporating the detailed provisions of the regulations defining adequate and well-controlled clinical investigations—are sufficiently specific to justify invocation of the summary judgment procedures.

Again, one can understand—indeed, even sympathize with—FDA's desire to avoid the administrative burden of publishing a detailed notice in every case. But the procedure adopted by the Agency in its new regulations for cases, in which there has been a general notice for opportunity for hearing, seems eminently fair and reasonable for cases in which there has been a specific notice too. For the plain fact is that it is not until the Agency's final order in efficacy review cases that the manufacturer knows specifically where the Agency believes his studies are deficient—which criteria of adequate and well-controlled investigations are deemed lacking and why. Since the Agency must write a detailed final order in any event to deny a hearing and grant itself summary judgment, the delay involved in giving the manufacturer, at that stage, a chance to respond to that order and meet the Agency's specific objections to his studies is quite small and, it seems to me, wholly justified.

Effect of the Cooper *Laboratories* Case

In the recent *Cooper Laboratories* case.[14] Judge Leventhal took just such a position, arguing that the manufacturer had not been given a sufficient opportunity to meet FDA's specific objections to his studies, and advocating the use of a proposed final order procedure to give manufacturers a meaningful opportunity to demonstrate the existence of disputed facts. The majority, however, while critical of the specificity of FDA's final order denying Cooper a hearing, upheld FDA's action. It is my understanding that Cooper plans to file a petition for rehearing *en banc*, so the last chapter in that case may not have been written. In any event, however, *Cooper* probably lays to rest permanently the original *USV* notion that a full *prima facie* case must be set forth in the original notice of opportunity for hearing. Given FDA's detailed definition of adequate and well-controlled clinical investigations, it seems highly unlikely that a manufacturer will, in the future, be able to prevail on an argument that a notice of opportunity for hearing, of the type generally used by FDA, is inadequate to shift to him the burden of coming forward with a detailed factual analysis of the studies upon which he relies.

Status of the Proposed Final Order

However, the argument that a proposed final order procedure is necessary to ensure fairness in the summary judgment procedure, in all cases in which the manufacturer has the initial burden of coming forward with his factual case, may not yet be dead. To be sure, if the panel decision in the *Cooper* case stands, the argument will be difficult. But it seems likely to me that there will be cases in the future in which a strong argument can be made that the manufacturer has been unaware of FDA's specific objections to his evidence until the final order stage.[15] In such cases, considerations of fundamental fairness may lead FDA to employ the proposed final order procedure even though it is not required by its regulations; and if FDA does not do so, the courts may yet step in. **[The End]**

[14] *Cooper Laboratories, Inc. v. Commissioner*, — F. 2d — (D. C. Cir. No. 72-1856), decided April 19, 1974.

[15] Or there may be cases, such as the recently-decided *Alcwaire* case (*Sterling Drug, Inc. v. Weinberger*, — F. 2d — (2d Cir. Nos. 73-1628 and 73-2481), decided May 2, 1974), in which a shift in FDA's basic theory of the case between the time of the original notice and final order will require that the manufacturer be given a second opportunity to establish a basis for a hearing.

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