VOL. 24, NO. 6 June 1969

Food Drug Cosmetic Law JOURNAL

Papers Presented at the FDA-Industry Atlanta Seminar on Labeling of Household Chemicals and Paints

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

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

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

June, 1969
Volume 24 • Number 6

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

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Food·Drug·Cosmetic Law Journal

The Benefits of Government / Industry Cooperation

By KERMIT V. SLOAN

This Paper and the Two Following Were Presented at the Food and Drug Administration Regional Seminar on Labeling of Household Chemicals and Paints, Held in Cooperation with the Chemical Specialties Manufacturers Association and the National Paint, Varnish and Lacquer Association, in Atlanta on February 5, 1969. Mr. Sloan Is Project Officer, Bureau of Voluntary Compliance of the FDA.

IT IS A PLEASURE FOR ME to appear on this program and speak to you briefly about the benefits of government/industry cooperation. This is a subject which, unlike many others—some Federal Drug Administration (FDA) regulations, for example—seems to be non-controversial. There can be little question, if any at all, that government/industry cooperation benefits not only government and industry, but, more importantly, the great American public—consumers, if you will. After all, the purpose of the law and regulations that we are discussing here today, indeed, the ultimate purpose of our being here together as representatives of government and industry is to benefit consumers.

What are the benefits to industry that are expected from this cooperative effort? You as businessmen who manufacture a great variety of household products which can be hazardous if mishandled or misused are interested, of course, in producing quality products and labeling them to conform with requirements of the law and government regulations. Above all, you do not want any of your

products to be responsible for injuries which can be prevented by proper labeling to identify potential hazards and provide suitable warnings and precautionary information.

The value to industry of such meetings I think is obvious. This one may help some of you to avoid violating the law unwittingly and thereby subjecting your company to product seizure or other legal action, with attendant economic loss and damage to your company's prestige.

What is the value of these meetings to government? It is frequently said that ignorance of the law is no defense if you violate it. This is true. But there is another side to the coin. We at the FDA believe that we should do everything possible to make sure that the industries subject to the laws we administer are provided with information—that they are given an opportunity to know what the law requires of them. Providing such information is the primary mission of the Bureau of Voluntary Compliance which I represent. And participating in meetings such as this is just one of many ways in which we try to make available to the regulated industries the information they need to understand the law and our regulations.

We happen to believe the old adage that an ounce of prevention is worth a pound of cure. Every legal action that we are able to prevent by our educational and information programs and by cooperative activities with industry groups results in savings of time and public money. Consumer protection is enhanced and, of course, industry is spared the expense of costly legal proceedings and damaged reputations. Thus, it is apparent that the government, the public and industry benefit substantially from our cooperative efforts.

As a matter of fact, entirely apart from the very obvious benefits of our working together, government/industry cooperation in this modern age is an absolute necessity if consumer protection is to be a reality and not just a catch-phrase. For example, consider this: Products covered by the laws enforced by the FDA have a sales value far in excess of 100 billion dollars annually. There are more than 100,000 factories and warehouses, and some 700,000 retail establishments subject to these laws. In contrast, FDA has fewer than 5,000 employees overall, in Washington and throughout the nation, to inspect food, drug and establishments to see that the consumer protection laws are observed. Simple arithmetic will indicate that without voluntary compliance by the overwhelming majority of the

companies in these vast industries—without government/industry cooperation—it would be a practical impossibility to marshall a sufficient force to police this great industrial complex.

Voluntary Compliance

For many years the FDA has subscribed to a creed enunciated in 1947 by the late former Commissioner Paul B. Dunbar. He said in part:

> We believe that most American manufacturers of foods, drugs, and cosmetics (and hazardous substances) have the scientific knowledge, the technical equipment, and the will to produce articles which meet both the spirit and letter of the law; that most American manufacturers recognize that consumer interest and producer interest are identical; and that practices adverse to consumer interest are likewise contrary to the interest of industry; and that most American manufacturers are making sincere and effective efforts to meet all legal requirements not only because they are the law but because it is the right thing to do.

Mr. Dunbar's statement is just as true today as it was 23 years ago. More than 95% of the companies subject to our jurisdiction want to, and do, voluntarily comply with the law. It is the small percentage of recalcitrants who deliberately fail or refuse to comply who must face the consequences of our enforcement action.

Former Commissioner Goddard, a few months ago, said that "FDA had a mandate not only to enforce the law, but also to inform; and one responsibility was not to cancel out the other. Rather, they were to be mixed in the proper amounts and necessary proportions."

Our alternative to enforcement procedures is a policy designed to encourage maximum self-regulation by industry. The basic tool used to promote voluntary compliance is communication. But it must be a two-way communication. There must be frank and open discussion; you will ask for our help and we will ask for yours. In this way we learn of the problems you face in attempting to comply. And we can better keep you up to date on what the law requires, what it prohibits, and how it applies to different products.

This conference today is a prime example of the kind of communication I am talking about. Here, through the presentations of your industry experts and your questions, we are getting a better idea of your problems. Likewise, through the FDA presentations and the panelists' discussions and answers to your questions I think both of us have gotten a better understanding of compliance problems and how to solve them. Some of your problems have been caused

by the very growth of your industry. There has been a tremendous increase in the number and types of chemicals used in the home. It is estimated that more than 50% of the products now sold by the chemical specialties and paint industries were not in commercial production in 1939. The average American home had about 10 chemical products on hand 20 years ago. Today the average home contains about 40 different chemical products. Along with technological progress and proliferation of different chemical products have come new plants, with new firms entering the field. Some of these new firms have been completely unaware of what the law requires.

History of Actions

To help us anticipate future problem areas, let us scan the record of past legal and other actions and the types of products involved. The first year that the Federal Hazardous Substances Labeling Act (now Federal Hazardous Substances Act) became effective, in 1962, there were 14 seizures of misbranded hazardous substances. These included 3 lacquer thinners, 2 of carbon tetrachloride, 3 of turpentine and 6 of soldering flux. In 1963 the number of seizures jumped to 59 and several additional products appeared on the list. These included water repellants, drain cleaners, model engine fuel, and floor cleaners. The 1964 total of 538 seizures included 504 seizures of X-33 water repellant. The X-33 episode involved a product so hazardous that no amount of cautionary labeling could make it safe for use. Under the Federal Hazardous Substances Act, as amended in November 1966, this product has now been banned by the Commissioner of Food and Drugs. Under the 1966 amendments, such action is based on a finding that, regardless of labeling, the hazard involved is so great that the public health and safety can be served only by keeping such a product off the market.

During the years 1965 through 1967, there were a total of 316 seizures. Included in the total were several special problems such as misbranded fireworks and flammable rag dolls. However, the yearly totals continued to include consumer household items such as paints, thinners, lighter fluid, cleaning compounds and household repair and care products.

In fiscal year 1966 there were 6 recalls of hazardous substances; and in fiscal 1967 there were 16. Most of these recalls were for misbranding. In fiscal year 1968 there were 9 recalls. Among the products involved were flammable and explosive oven cleaners, a rust stain

remover with inadequate warnings, a windshield de-icer packaged in over-pressurized cans, a stain remover and polish, both of which carried inadequate warnings; and children's toys containing methanol or methyl alcohol.

These statistics show that industry continues to have some problems with compliance. But the problems could have been far greater had not steps been taken to acquaint industry with the requirements. Industry guidance has come from the industry itself, through its trade associations, and from FDA. You all are aware, of course, of the excellent labeling guides prepared by the National Paint, Varnish and Lacquer Association, the Chemical Specialty Manufacturers Association and the Manufacturing Chemists Association. These labeling guides represent an outstanding example of self-regulation by an industry. The associations recognized in some cases even before the Federal Hazardous Substances Act was enacted that their members, while generally willing to properly label their products, were very much in need of guidance.

The Spirit of the Law

Before closing I would like to leave with you one further thought. We have talked here about compliance with the law. By that usually is meant compliance with the letter of the law. Seminars such as this are designed to promote such compliance. Industry can go beyond this and consider the spirit of the law with its larger social obligations. In our modern society, private enterprise is being called upon more and more to share with government responsibility for solving the great social problems.

New products go on the market at such a rapid rate that the possibility always exists that a substance too hazardous for public use might unintentionally be made available. FDA now, of course, may ban such a product regardless of labeling, but this is equivalent to closing the barn door after the horse has run away. In this regard, labeling which meets the letter of the law does not change the danger inherent in a hazardous substance. Therefore, you might want to consider such things as safety closures on certain products, or some type of limited flow closure so that the total content of a container will not be readily accessible.

Recently, several drug chains began placing safety closures on all bottles of tablets and capsules. This is not required by the Fed-

eral Food, Drug and Cosmetic Act but is definitely in the public interest; and it is a prime example of action taken in the spirit of the law. As you know, many companies regularly place public service ads in magazines. Two trade associations, the National Agricultural Chemicals Association and the Animal Health Institute have recently adopted eye-catching symbols cautioning users of their products to observe label directions and are using these in communications, packaging and promotional materials. There is no requirement either in the Federal Insecticide, Fungicide and Rodenticide Act or the Federal Food, Drug and Cosmetic Act to have such reminders for pesticides or veterinary drugs and medicated feeds. But education of users of such products is viewed as a social obligation. And, looking at it purely from a business standpoint, it could be that this kind of public service enhances the saleability of products. Consumers are quick to recognize and respond to action taken voluntarily in their interest. **[The End]**

Revised Prescription Drug Advertising Regulations Issued by FDA

Prescription drug advertising that is truthful, fairly balanced, and informative is the theme of the final prescription drug advertisement regulations issued by the Food and Drug Administration to revise and clarify its regulations published in June, 1968. The revisions, which set forth guidelines for the type of information that must be included in drug advertising and the advertising practices that must be avoided with prescription drugs, are the result of objections filed by the Pharmaceutical Manufacturers Association to the regulations issued in 1968.

The revised regulations require drug manufacturers to include information in advertisements using radio, telephone and television communications on a drug's major side effects and contraindications. If the manufacturer does not also adequately disseminate the FDA approved package labeling of the drug in connection with the broadcast presentation, then a brief summary of all necessary information related to side effects and contraindications must be included in the presentation.

In addition to twenty prohibited practices which would make an ad false, lacking in fair balance, or otherwise misleading, the regulations include thirteen other practices that could result in a violation of the Federal Food, Drug and Cosmetic Act.

Under the revised regulations, a particular drug advertisement could include a prohibited practice if prior written approval is obtained from the FDA.

Reg. § 1.105e, CCH Food Drug Cosmetic Law Reports ¶ 9922.

How to Label Products Under the Fair Packaging and Labeling Act

By F. DALLAS SPARRE

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THE FAIR PACKAGING AND LABELING ACT (FPLA)—Public Law 89-755—was approved November 3, 1966, and became effective July 1, 1967. However, The Secretaries of Health, Education and Welfare (HEW) and Commerce and the Federal Trade Commission (FTC) had to promulgate regulations before there was anything to comply with, so effective dates vary from December 31, 1967, to July 1, 1969, depending on the consumer commodity specified.

Congress declared the purpose of the Act—nicknamed from the early days, among other titles, as "Truth-in-Packaging"—to be that packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons. The Act is on the books, certain regulations have been published in final form; and we now examine what must be done to labels to have them comply.

You will not ordinarily be able to prepare a complying label for a consumer commodity or be fully aware of exemptions and special situations solely from the information contained in this paper. You should write to the enforcing agencies for a copy of the law and their respective regulations and request each that you be placed on their mailing list to receive new and amended requirements. (You will also need a tape measure or flexible ruler graduated in sixteenths of an inch.)

The Act covers consumer commodities in interstate commerce whether packaged or merely labeled and defines them as any food,

drug, device, or cosmetic (as they are defined in the Federal Food, Drug and Cosmetic Act) and any other article, product, or commodity of any kind or class which is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which usually are consumed or expended in the course of such consumption or use. Articles expressly exempt include: (1) any meat or meat product, poultry or poultry product, tobacco or tobacco product, (2) any commodity subject to the Federal Insecticide, Fungicide, and Rodenticide Act or the Virus-Serum-Toxin Act, (3) any drug subject to section 503 (b) (1) or 506 of the Federal Food, Drug and Cosmetic Act, (4) any beverage subject to the Federal Alcohol Administration Act, or (5) any commodity subject to the Federal Seed Act.

"Package" means any container or wrapper in which any consumer commodity is enclosed for use in delivery or display to retail purchasers but does not include shipping containers or wrappings used solely for transport to non-consumers or to wrappings used by retailers to deliver a commodity to retail customers. Commodities in standardized berry and fruit baskets are exempt. Included in consumer commodities that are not packaged but are merely labeled would be items such as brooms and tools.

The Act required that the commodity bear a label specifying the identity of the commodity and the name and place of business of the manufacturer, packer, or distributor; the net quantity of contents in terms of weight, measure, or numerical count which shall be separately and accurately stated in a uniform location on the principal display panel; this separate statement is required to be in both total avoirdupois ounces as well as pounds (with necessary ounces or fractions of pounds), if the total quantity is at least one pound but less than four pounds, or in total fluid ounces as well as pints or quarts if the total quantity is at least one pint but less than one gallon. Commodities sold by linear or area measure also require dual declarations within similar limits.

A long standing requirement has been included in that the declaration of contents shall be conspicuous, easily legible, and in distinct contrast by typography, layout, color, embossing, or molding with other matter on the package.

The Act requires that the letters or numerals used in the content statement be in a type size which shall be established in relationship to the area of the principal display panel and uniform for all packages of substantially the same size and that the lines of printed matter be generally parallel to the base on which the package rests as it is designed to be displayed.

Also required is a statement of the net quantity of each "serving" if the label bears any representation as to the number of servings in the package.

The Act defines a random package as one of a lot or shipment of the same commodity with no fixed weight pattern and permits the declaration of quantity (if more than one pound) in terms of pounds and decimal fractions.

The Act prohibits the use of any qualifying words or phrases with the contents statement which tends to exaggerate the amount of commodity contained in the package but does permit supplemental statements in non-deceptive terms elsewhere than on the principal display panel.

The Act requires that if either the Secretary of Health, Education and Welfare or the FTC determines that other requirements are necessary to prevent deception, the agency may require the label to bear the common or usual name of the commodity and if it contains two or more ingredients, the common or usual name of each such ingredient, but they cannot require divulgence of trade secrets.

The Secretary of Commerce is authorized to determine whether there is undue proliferation of weights, measures or quantities of any consumer commodity or comparable consumer commodities which would impair the reasonable ability of consumers to make value comparisons. If he so determines, he may request manufacturers, packers, and distributors of such commodities to develop a voluntary standard for reducing the proliferation. If this meets sufficient resistance, the Secretary is required to report to Congress that a standard is not likely to be developed (or a developed standard is not being followed) and recommend amendatory legislation.

The three federal agencies involved have issued regulations for detailed compliance with most of the aforementioned requirements of the Act and for complete or limited exemptions for some commodities. But to our knowledge, neither HEW nor FTC have pro-

posed regulations for three other requirements if the agency determines that more is needed to prevent deception. These are (1) establish and define standards for characterizing sizes of packages, such as "small", "medium", or "large"; (2) regulate things, such as "cents-off" promotions; and (3) prevent non-functional-slack-fill.

Regulatory Requirements

While the regulations issued by HEW and FTC are not identical in all respects—primarily due to special features of foods, drugs, devices, and cosmetics and the requirements of the Federal Food, Drug and Cosmetic Act—it is reasonable to suggest that if the following regulatory requirements are adhered to, an acceptable label can be prepared.

1. The principal display panel is that surface most likely to be displayed or examined under customary conditions of retail sale. It must be large enough to accommodate all mandatory label information required to be on that panel with clarity and conspicuousness, uncluttered by fancy background designs or crowding. In the case of very small containers a firmly attached tag may be used. The label need not cover the entire panel of the package, but the area of the package panel itself—not a label patch—must be used for determining type size of the quantity statement. Alternate principal display panels frequently occur because of package information layout and if so, each must contain all the required information.

In the case of a rectangular package, one entire side can properly be considered principal, and the area would be the height times the width of that side.

In the case of a cylindrical or nearly cylindrical container, the area is 40% of the height times the circumference.

In the case of any other shaped container, the area is 40% of the total surface of the container.

In the case of a commodity mounted on a display card (such as blister pack), the dimensions of the card constitute the area.

In determining area, you may exclude tops and bottoms and flanges at tops and bottoms of cans and shoulders and necks of bottles or jars.

2. The quantity statement must appear within the bottom 30% of the principal display panel, generally parallel to the base on

which the package rests and be in characters of a height in relation to the package panel area as follows:

not less than 1/16 inch for an area 5 square inches or less;

not less than ⅛ inch for an area 5 to 25 square inches;

not less than 3/16 inch for an area 25 to 100 square inches;

not less than ¼ inch for an area over 100 square inches; except

not less than ½ inch height if the area is more than 400 square inches.

Where the statement is blown, embossed or molded in a glass or plastic surface, increase each character size by 1/16 inch.

Letter heights are for capital letters, but if initial capitals and lower case or all lower case are used, the lower case "o" shall meet the minimum size. Fractions shall equal half the height of the main characters.

The quantity statement shall be on a plain contrasting background separated above and below by at least the height of the characters used, and by at least twice the width of the letter "N" of the characters used to either side from any other printed matter on the label.

The characters may not be more than three times as high as they are wide. The requirement that the characters be in bold type refers to conspicuous display and *not* a printing trade designation of type face. The quantity statement may not be qualified by exaggerated statements, such as "when packed," "minimum," "giant gallon," "full quart," or terms of similar import. However, it may be supplemented in non-deceptive terms on another panel. Dual declarations when required, metric equivalents, dilution directions, and similar statements are not considered supplemental declarations.

3. The quantity statement shall be expressed in terms of the avoirdupois pound and ounce for "net weight," and *this term* must be used with the statement. Statements of fluid measure shall be in terms of the U. S. gallon and the pint, quart, and fluid ounce subdivisions thereof; and it is *not* mandatory to use the term "Net Contents." Except in the case of petroleum products for which the declaration shall be by volume at 60°F., the quantity shall be expressed at 68°F. Statements of linear measure shall be in terms of yards, feet, and inches. Statements of dry measure shall be in terms of the U. S. bushel and the peck, dry quart, and dry pint subdivisions thereof. Statements of cubic measure shall be in terms of the cubic yard,

cubic foot, and cubic inch. Specified abbreviations of these terms are permitted.

The statement shall, as always, be made in terms of the largest whole unit with any excess in terms of the next smaller unit. Where common fractions are used, they shall be reduced to their lowest terms in halves, quarters, eighths, sixteenths and thirty-seconds. Decimal fractions may be used but shall not be carried out to more than two decimal places.

4. The statement of quantity shall accurately reveal the quantity of commodity in the container exclusive of wrappers *except that labels for self-pressurized containers shall declare the quantity that will be expelled when the directions for use are followed. The propellant is included in the quantity statement which shall be by net weight.*

Variations from the stated quantity shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting which occur in good manufacturing practices, but such variations shall not be permitted to such an extent that the average of the quantities in the packages comprising a lot or shipment is below the stated quantity. No unreasonable shortages are permitted at any time and cannot be compensated for by overages in other packages in the lot. Variations shall not be unreasonably large.

5. If the commodity is in distinct usable units made up of more than one component or ply, the quantity statement shall—in addition to the area measurement of each unit—state the number of usable units and the number of ply.

6. If the label bears any representation as to the number of servings, uses or applications, such representation shall be augmented —immediately in conjunction therewith—by a statement of the quantity in terms of weight, measure, or count of each such serving. However, common terms, such as cupful and tablespoonful, may be substituted here.

7. Transparent wrappers or containers which do not bear written, printed or graphic matter obscuring any part of the required label information are exempt from the marking requirements. A container sold in an outer wrapper or box which is marked to comply fully with the requirements *does not have to meet type size or placement provisions.*

8. A specification of identity shall appear as a principal feature of the principal display panel and be so placed in large type as to be easily read and understood. It shall also be in lines generally parallel to the display base.

Terms used shall be either a name specified by any applicable Federal law or regulation, the common or usual name of the commodity, a generic name, or another appropriately descriptive term, such as a term which includes a statement of function. Ingredients or components which are not present in substantial or significantly effective amounts may not be mentioned in the identity statement.

9. The name and place of business of the manufacturer, packer, or distributor must appear conspicuously somewhere on the label; and if the name is not that of the manufacturer, it must be qualified by a phrase which reveals that person's connection with the commodity. Terms, such as "Manufactured for," "Packed for," "Distributed by," are acceptable.

In the case of a corporation, the name shall be the actual corporate name—divisional designations may be included. In the case of an individual, partnership, or association, you must use the name under which the business is conducted.

The place of business shall include city, state, and zip code. The street address must also appear if it is not available in a current city directory or telephone directory.

Unless such statement would be misleading, the address may be the principal place of business rather than a specific manufacturing, packing, or distributing point.

10. With respect to ingredient declarations on food labels, the regulations for the Federal Food, Drug and Cosmetic Act are augmented by a requirement that in the case of fabricated foods or mixtures a quantitative declaration shall be required for certain expensive ingredients if necessary to avoid creating the impression that more is present than is really there.

Other Details

Many requests have been made to HEW and FTC for complete or partial exemption from the labeling requirements of the act and regulations and a number have been granted. The usual partial ex-

emption request has to do with dual declaration, type size, and the bottom 30% of the main panel. These have been granted for anti-freeze, coffee, butter, milk, wheat flour products, and a number of others. Ice cream and similar frozen products are exempt from dual declaration, and they may use the terms ½ pint and ½ gallon instead of 8 oz. and 64 oz.

FTC has declared a large number of commodities to be covered by the Act following requests for full exemption but has indicated they would be inclined to rule favorably on requests for partial exemptions.

Don't forget that the various state and municipal weights and measures laws are still in effect for interstate products to the extent their requirements do not differ from the Federal requirements. For intra-state consumer commodities and all non-consumer commodities they are fully effective. The National Conference of Weights and Measures, at its annual meeting in June, 1968, adopted revised model regulations substantially conforming to Federal requirements; and you may expect these to be adopted fairly rapidly by the states and municipalities.

The National Bureau of Standards of the Department of Commerce has been holding informal meetings with various industry segments in an attempt to begin correcting areas where there seems to be undue proliferation in packages of the same class of commodity. To date, we are aware only of informal tentative agreements to reduce the number of package sizes. We believe no one has yet found it necessary to go through the entire voluntary standardization procedures. Commodities in process of "deproliferation" so far include toothpaste, salad oils, powdered coffee, some detergents, and cereals.

As a final wrinkle, the Internal Revenue Service, Alcohol and Tobacco Tax Division, has ruled that denatured spirits (not booze) are to comply with FPLA.

In the time allotted we have not tried to cover every detail spelled out or implied in the regulations. We believe we have covered the important items and indicated the range of details. It is strongly recommended that you consult trade association bulletins and with counsel and industry associates before releasing final label copy. **[The End]**

FHSA: Requirements and Exemptions

By DALE C. MILLER

Mr. Miller Is the Assistant to the Director in the Division of Case Guidance, Bureau of Regulatory Compliance, FDA.

BASICALLY, THE FEDERAL HAZARDOUS SUBSTANCES ACT (FHSA) applies to containers intended or packaged in a form suitable for use in the household or by children. This is quite a broad definition and some further explanation is probably necessary in order to clarify its meaning. According to our regulations (Section 191.1(c)), "Hazardous substances intended or packaged in a form suitable for use in the household means any hazardous substance that under customary or reasonably foreseeable conditions of purchase, storage or use may be brought into or around a house, apartment, or other place where people dwell or in or around any related building or shed, including but not limited to a garage, carport, barn or storage shed." In our opinion, this includes farms, apartments, and schools. It does not include substances taken into a household by a serviceman or a repairman, nor does it include industrial articles that may be misappropriated by a worker for his own use. If there is any doubt about the availability of your product for sale to householders, we believe that the question should be resolved in favor of the public by applying appropriate cautionary labeling.

There are also circumstances where it may be advisable to label large containers of substances, even though they are obviously not intended for household use. For example, a 55 gallon drum of a hazardous dry cleaning solvent would not normally be regarded as a household item, but where such containers may be sold for repacking or for use as a component of a mixture for household use, we believe it would be prudent to apply cautionary information; this would serve not only as a warning for the individuals doing the

repacking or formulating, but would also provide them with labeling that would be appropriate for the repackaged product, or at least helpful to them in devising appropriate cautionary labeling for the new mixture.

I mentioned that the Act applies to hazardous substances intended for use in or around the household. However, there are some exceptions.

Quite often there are substances or mixtures of substances that are toxic, irritant, flammable, or possess other hazardous properties, but are not required to bear warning statements under this Act. These, of course, are the exempted articles and fall into two categories: those exempted by the *statute,* and those exempted by the *regulations.* Based on the number of inquiries received over the years, considerable confusion seems to exist, so let us take a look at those exemptions, starting with those in the statute.

Exemptions in the Statute

Section 2(f)(2) states "The term 'hazardous substance' shall not apply to economic poisons subject to the Federal Insecticide, Fungicide and Rodenticide Act." This is clear enough with respect to insecticides, fungicides and rodenticides, but it also includes some other classes of products that are not so clear. For example, if a container of a hazardous household product bears directions for use only as a bleach, or room deodorant, or cleanser, it is subject to consideration under the Federal Hazardous Substances Act, but if the same product bears label directions for use as a "disinfectant" or "sanitizer," it must be registered and approved by the United States Department of Agriculture under the Federal Insecticide, Fungicide and Rodenticide Act and is exempt from the FHSA. The same thing is true with respect to a can of paint sold with claims that it will prevent mildew, or kill insects, or keep barnacles and seaweed off a ship's bottom. Or, in the case of a product that is dumped down the drain, if it merely cleans out the plumbing, it falls under the FHSA, but if it is claimed to kill roots, it is exempt and subject to the Federal Insecticide, Fungicide and Rodenticide Act. That Act also requires cautionary labeling but differs from the FHSA in that specific approval of a label is required, whereas under the FHSA the responsibility for meeting the requirements of the law rests with the sponsor of an article.

Also exempted from coverage under the FHSA are "foods, drugs and cosmetics subject to the Food, Drug and Cosmetic Act."

More and more drug and cosmetic products, and even foods, are being sold in pressurized containers. We all know that these possess a degree of hazard, and Section 191.110 of the hazardous substances regulations specifies an appropriate warning. But what about hair sprays, cans of shave foam lather, or even cans of whipped cream? Do they not have the pressure hazard (and possibly other hazards) also? Yet, since these are subject to the Food, Drug and Cosmetic Act, they are not required to bear a pressure warning. Bills have been before Congress which would amend the law to require cautionary labeling on hazardous articles subject to the Food, Drug and Cosmetic Act, but until some such amendment is passed, we cannot insist on warnings except in certain specific cases, such as "Dispensers Pressurized by Gaseous Propellants for Drugs for External Use" (Section 131.15). We do, however, urge that the manufacturers and distributors voluntarily use a warning in the public interest and a good many firms do so.

The law also exempts "substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house," as well as "any source material, special nuclear material or by-product material as defined in the Atomic Energy Act of 1954." I don't believe there is much confusion about these exemptions so I'll move on.

Exemptions in the Regulations

So much for the exemptions in the Act. Now let's look at the exemptions in the regulations. These exemptions are listed in Section 191.63 of the regulations and some 35 or 40 have been granted. It might be worth while to look at a few of them to see the basis for them:

Matches, paper items, thread and twine, etc., are probably all "flammable" or "extremely flammable" but this is such common knowledge that a warning would serve little or no useful purpose. (Section 191.63(a)(2)(3) and (4)).

The ink in ballpoint pens is sometimes very toxic and could cause injury if ingested, but because of the construction of ballpoint pens, ingestion is very unlikely (Section 191.63(a)(7)).

Porous tip ink-marking devices often contain over 10% xylene and according to the regulations they should, therefore, bear ingestion and hazardous vapor warnings. But if the xylene is all absorbed into a porous material and can only come out

through the tip, there is no ingestion hazard. Further, the amount of xylene in each pen is so small that even if it all evaporated into the air at one time, it is not likely that a harmful level of vapor would be reached (Section 191.63(a)(9)).

Certain asphalt emulsion adhesives contain more than 4% by weight of methyl alcohol and according to the regulations would need special labeling unless exempted. Most of the adverse human experience with methyl alcohol has resulted from drinking potable forms of the chemical. Ingestion of enough black sticky adhesive to obtain a harmful amount of methyl alcohol is extremely remote, at best, so an exemption regarding ingestion was granted, but the label was required to bear some cautionary statements as to adequate ventilation (Section 191.63-(a)(34)).

Occasionally certain types of products are sold in the form of a kit containing two or more containers of hazardous substances. Literally interpreted, the Act would require that the outer carton bear several warnings, one for each container of a hazardous substance in the kit. However, we received requests to grant an exemption that would permit a single warning calling attention to the fact that the kit contains certain hazardous chemicals and that the warnings on the individual containers should be carefully read. This was a reasonable request and the exemption was granted (Section 191.63(a)(25)).

These few examples may give you some idea of the types of exemption that are possible. But before leaving this subject, I wish to emphasize that most of the exemptions granted have one or more conditions that must be met. Then, anyone who has a product meeting the conditions of the exemption may take advantage of it, not just the petitioner. And you don't have to have a lawyer to ask for an exemption, although an experienced one can be very helpful.

The next question may be how one goes about getting an exemption. Regarding this, Section 3(c) of the Act states:

If the Secretary finds that, because of the size of the package involved or because of the minor hazard presented by the substance contained therein, or for other good and sufficient reasons, full compliance with the labeling requirements otherwise applicable under this Act is impracticable or is not necessary for the adequate protection of the public health and safety, the Secretary shall promulgate regulations exempting such substances from these requirements to the extent he determines to be consistent with adequate protection of the public health and safety.

Section 191.1(f) of the regulations specifically provides for consideration for exemption of toxic substances in the LD/50 range of 500 mg to 5 gm per kilo of body weight of test animals, when, because of the physical form of the substance, the size or closure of the container, human experience with the substance, or other relevant factors, it can be shown that the statutory labeling is in whole or in part not necessary. Similar consideration will be afforded substances which are irritant, corrosive, flammable, strongly sensitizing, or that generate pressure.

You should request an exemption by a petition, which may be in the form of a letter directed to the Commissioner of Food and Drugs. Without full information about your product it is difficult to be entirely specific as to just what information should be submitted in the petition. Generally speaking, however, we would suggest that any petition include the following items:

(1) The complete quantitative formula (percentage by weight) of the product and a brief description of the method of manufacture. (Formula information is held strictly confidential.) Each ingredient should be designated by its chemical name (*trade names are not sufficiently informative*).

(2) Complete labeling now applied and that intended to be applied if the exemption is granted. This should include all collateral labeling which would include directions for use. Labels submitted should include all sizes for which exemption is requested. Include a brief description of the package.

(3) Complete toxicological reports of tests on animals. If such data are not available on the finished product, you may submit toxicological information on the ingredients. If published data are involved, reprints should be submitted where the particular publications are not generally available.

(4) Physical data. Specific gravity, flammability, viscosity, and pH of the substance (if water soluble) at a given concentration.

(5) Human experience. Include a description of any difficulties your employees have experienced and a *complete* listing or summary of injury complaints received from users of the product. Any data from controlled human experience should be included.

(6) Samples. Samples should be submitted when the size, form or construction of the container or the type of closure is

an important part of the petition. Empty containers may be submitted for labeling. Physical samples of the product should accompany the petition when the physical state of the product is an important consideration.

(7) A summary outlining the reasons why you believe the particular exemption you request should be granted.

We realize that all of the listed items may not be appropriate for every product for which an exemption is requested and we can visualize situations where some of the toxicity data, for example, might not be a necessary factor in the evaluation of a particular substance. Perhaps the best way to proceed would be to supply information under each heading where it is available and state why you are not supplying the other information. Then, if on evaluation of your petition we conclude that some additional information is needed, we will promptly notify you.

When a final decision has been made on your request, either a regulation granting the exemption will be published in the *Federal Register* and you will be so notified, or you will be advised that your request has been denied.

Let's take a look at what type of cautionary information must be on the label of household products subject to the FHSA. The requirements, in general, are all specified in Section 2(p)(1) of the Act, but let's take a look at them one by one.

Label Requirements

As an example, let's take a common household product, a liquid bleach containing about 5% Sodium Hypochlorite (As I mentioned earlier, this could be subject to the Federal Insecticide, Fungicide and Rodenticide Act if it bears disinfectant or sanitizer claims, so we'll assume it is labeled only as a bleach).

SIGNAL WORD (2(p)(1)(C) or (D)): Because the only hazard involved with this type of bleach is that it is an "irritant", the signal word "CAUTION" or "WARNING" may be used. As a general rule one or the other of these signal words (the Act gives a choice) is acceptable for substances that are toxic, flammable, irritant, strong sensitizers or pressure generating substances; for highly toxic, extremely flammable or corrosive substances, "DANGER" must be used. Highly toxic substances must also bear the word "POISON" and the skull and crossbones.

However, there are some exceptions to the foregoing. The word "POISON" (without the skull and crossbones) is required on the 12 caustic substances formerly subject to the Federal Caustic Poison Act, instead of a signal word (Section 191.109). Also, Section 191.7(b) specifies special labeling for Methyl Alcohol, certain petroleum distillates, carbon tetrachloride, turpentine and ethylene and diethylene glycols.

The signal word must be printed in capital letters, must appear on the main panel or panels and should be in 18 point type, unless the label space is too small, in which case it may be reduced. I'll say more about type size and conspicuousness a little later.

STATEMENT OF PRINCIPAL HAZARD OR HAZARDS (2(p)(1)(E)): In this case, there's only one: "IRRITANT"; but for some products, depending on the composition, there may be two or more, including statements such as FLAMMABLE, VAPOR HARMFUL, CAUSES BURNS, HARMFUL OR FATAL IF SWALLOWED, or similar wording descriptive of the hazards. These statements should also be on the main panel(s), in capital letters and should be in 12 point type unless available label space is too small.

The rest of the cautionary labeling may also be on the front panel, but it does not have to be. The balance may be on a side or rear panel, provided the label calls the reader's attention to this fact. A statement such as "Read carefully cautions on back panel" would do. The rear or side panel cautionary information should be printed in 10 point type unless the available label space is too small, in which case it may be reduced, but it should be no smaller than the rest of the type on the panel. The information should be printed "together" without intervening printed or graphic matter and should be made conspicuous, not hidden. If this cannot be done by appropriate typography, the information should be within a borderline.

NAME OF HAZARDOUS INGREDIENT(S) (2(p)(1)(B)): This information is indispensable when there has been an accident and enables the physician to start any necessary treatment promptly, without having to waste valuable time trying to find out what is in the product. It should, therefore, be as specific as possible, keeping in mind its purpose. If a product contains perchloroethylene, it should be declared as "perchloroethylene" and not "organic solvents" or "chlorinated solvents," as we have seen on a number of labels.

INSTRUCTIONS FOR SPECIAL HANDLING OR STORAGE (2(p)(1)(I)): This may not always be necessary, but in the

case of our bleach we believe it is, and recommend the statement, "Do not mix with acids or other household chemicals." We believe this statement is necessary because when hypochlorite bleach is mixed with acid, dangerous chlorine gas is liberated. Other chemicals, such as certain types of detergents, and ammonia, are also known to cause similar reactions, and we have had a number of reports of injury and complaints.

Other examples are "Keep away from heat and open flame," "Do not allow water to get into container" and the like.

PRECAUTIONARY MEASURES TO BE FOLLOWED (2(p)(1)(F)): "Avoid contact with skin, eyes and other mucous membranes" is a statement intended to supplement the statement of hazard by setting forth, briefly, measures to be taken to avoid injury or damage from the stated hazards. Appropriate statements for other products might be "Avoid breathing dust," "Do not take internally," or "Use only in a well-ventilated area."

FIRST AID WHEN NECESSARY OR APPROPRIATE (2(p)(1)(G)): This is intended to instruct the householder as to appropriate first aid, should there be an accidental exposure. It should be simple enough for a rattled mother to be able to follow, and should utilize things that are readily available in a household—water, milk, vegetable oil, fruit juice, baking soda, etc., as appropriate. Sometimes the best advice is to leave all treatment to the doctor because any treatment the mother could give might do more harm than good. For example, for low viscosity petroleum distillates the first aid statement, "If swallowed do not induce vomiting. Call physician immediately." is required. To do something that might induce vomiting could in turn cause a fatal chemical pneumonitis by causing some of the product to get into the lungs.

KEEP OUT OF THE REACH OF CHILDREN (2(p)(1)(J)): This statement or a practical equivalent is required. If every user of a household product would follow this rule, there would be very few children injured from household products.

I mentioned certain type sizes earlier, but there is more involved in proper labeling than type size alone. The regulation specifying type sizes is somewhat loosely worded. This is because it is intended primarily as a guide to assist interested persons in meeting

the requirements of the statute that the cautionary information be stated *conspicuously*. As you will recognize, conspicuousness involves various factors such as color, style and boldness of type, and overall label design, in addition to the height of the lettering. For this reason, we prefer to evaluate the overall impact of the cautionary statements, rather than to try to set a minimum standard based on type size alone.

I have seen containers where the signal word was in 18 point type but was less conspicuous than other containers where the signal word was in smaller type. For example, I found that the word DANGER in 18 point dark blue type on a lighter blue background, or in red type on a mirror-like reflected background, is not only inconspicuous. but almost invisible.

Some time ago, we considered a request from an industry group that the regulations be revised to set certain type sizes based on the size of the label front panel in square inches. For the foregoing reasons, it was finally decided to leave the regulation unchanged.

The Act also calls for the name and place of business of the manufacturer, packer, distributor, or seller. There are no placement or type size requirements in the hazardous substances regulations for this information. However, the regulations promulgated under the Fair Packaging and Labeling Act (16 CFR Section 500.5) do have some requirements.

In addition to appearing on the labeling of the immediate container, the required warnings must also appear on the outer retail carton and on any accompanying literature that bears directions for use.

In leaving my topic, I call your attention to Section 191.108 of the regulations which states:

The Commissioner will offer informal comment on any proposed label and accompanying literature involving a hazardous substance if he is furnished with: (a) Complete labeling, which may be in draft form. (b) Complete quantitative formula. (c) Adequate clinical, pharmacological, toxicological, physical, and chemical data applicable to the possible hazard of the substance. (d) Any other information available that would facilitate preparation of a suitable label, such as complaints of injuries resulting from the product's use, or other evidence that would furnish human-experience data.

We are always glad to work with you and to help you comply voluntarily, since this is obviously to our mutual advantage.

[The End]

Procedural Reforms in FDA Hearing Procedures

By WILLIAM R. PENDERGAST

The Following Report Was Delivered Before the Food and Drug Committee, Federal Bar Association, April 29, 1969. Mr. Pendergast Is a Member of the Condon, McMurray and Pendergast Law Firm, Washington, D. C.

A SPECIAL COMMITTEE HAS BEEN FORMED to consider the situation at the Food and Drug Administration (FDA) with regard to its administrative hearings and to propose, where indicated, improvements either by way of regulatory modification or, if necessary, new legislation. Such improvements in these procedures would hopefully achieve the desired result of fair and, at the same time, manageable and expeditious hearings.

The other members of our Committee are Walter E. Byerley, Michael F. Markel, Vincent A. Kleinfeld, Selma Levine, H. Thomas Austern, Daniel Marcus, Charles W. Whitmore, Franklin M. Depew, Alan Kaplan, and Rodney Munsey.

We have considered and debated at some length many possible techniques ranging from legislative proposals to drastically revise the entire statutory setup to the more mundane matters of how to control cross-examination and how to conduct meaningful pre-hearing conferences.

Problems of Attitude

However, before I get into the various techniques under consideration, there is a preliminary matter which I should like to discuss. The more I look into this situation and the more I consider it, the more it becomes apparent that the problems with FDA administrative hearings are not necessarily problems of insufficient procedural techniques or too many procedural techniques but are often problems of attitude. It is the fashion to describe these procedures as fact-finding hearings at the administrative level; that the goal to be

achieved is a record containing the best possible evidence concerning whatever regulations are at issue; and that, therefore, the normal rules of courtroom evidence and procedures should not and are not designed to apply. But when you get down to the actual conduct of such a hearing you often find that the testimony and other evidentiary material is presented in the most adversary atmosphere possible. Witnesses are presented, not for the purpose of placing in the record that witness's entire expertise in the relevant area, but for the purpose of presenting only that part of the witness's opinions which support the proponent's position. Authorities in various scientific disciplines are often surprised to find that their entire testimony is not desired and that because of the narrow area in which they often do testify, it becomes impossible to place into the record the complete thinking of these men relative to the regulations in issue. Also, there very often is a lack of openness as to what is being attempted. There is an unwillingness at the hearing to face up to the real purpose of these hearings, that is, to lay the entire evidence on the record. This unwillingness and this adversary attitude in the actual conduct of the hearings by FDA leads to a sense of distrust and suspicion on the part of any parties present at the hearings and forces counsel to take an equally adversary position.

Therefore, no matter what techniques we develop, the hearings will continue to be unnecessarily adversary and protracted unless and until all the parties to these hearings recognize certain fundamental considerations which must be followed. First of all, the attorneys who bear the burden of proof in these hearings must be prepared to be completely candid about their positions; about the precise fact issues they believe they can support and the manner in which they intend to support them. There must be no surprises or tricks when the hearing actually begins. Counsel for parties opposing regulations must be equally candid when their time comes. All of the attorneys and their clients, whether in the FDA or out, must be willing to recognize these hearings for what they are and not allow these proceedings to degenerate into a button, button, who's got the button game. If they will recognize this and particularly if the FDA will approach the actual conduct of these hearings with the attitude of encouraging experts to attend and present their *entire* views, then a good deal of the adversary nature of hearings to date will disappear, for there simply will no longer be a need for it.

But, of course, procedural problems will not entirely disappear, and it would be utopian on my part to expect that all counsel will

voluntarily cooperate to the fullest possible extent. Some procedures will always be needed to control proceedings in a meaningful manner. The problems also will not go away for the simple reason that these hearings are now and will continue to be extremely complex.

In fact, one of the reasons for administrative hearings has always been a Congressional recognition that there are matters which should be held in some sort of public forum, but that they were too burdensome for the court system. Furthermore, as another writer has pointed out, protracted administrative hearings may be inevitable in this modern world. As he said:

> Society is more complex, and our realization of its complexity is more vivid, with the result that it becomes increasingly difficult to isolate single issues out of the interlocking web of events and circumstances which shape it.[1]

This is certainly the case today at FDA which, as we know, is now concerned with regulating our entire environment.

Improved Techniques for Hearings

Therefore, even if we do achieve a greater attitude of openness in FDA hearings, improved techniques of actually conducting such hearings must still be formulated. Unfortunately, they are not now explicit in FDA regulations, and attempts to bring new ideas into hearings on an ad hoc basis have proven unsatisfactory. Most of the suggestions which we are currently debating are those which will better control the actual conduct of hearings and eliminate confusion. The key to improving our hearings is to require disclosure by all parties of their evidence prior to the actual hearing itself. This can be done in a number of ways. Discovery techniques, where feasible under current FDA law, can be utilized; pre-hearing conferences can be brought to bear by using them as vehicles for requiring the parties to concede non-disputable fact issues; and the use of written direct testimony submitted well before the hearing can also be considered.

A well conducted pre-hearing conference is perhaps the most sensible, direct and best solution.[2] This requires that, when the first pre-hearing conference is held, all the attorneys are completely pre-

[1] Gardner, "Shrinking the Big Case," 16 *Administrative Law Review* 5 (1963).

[2] Gallagher, "Use of Pre-trial as a Means of Overcoming Undue and Unnecessary Delay in Administrative Hearings," 12 *Administrative Law Bulletin* 44 (1959-1960); Cox, "Adherence to the Rules of Evidence and Federal Rules of Civil Procedure as a Means of Expediting Proceedings," 12 *Administrative Law Bulletin* 5 (1959-1960).

pared with their cases so that they can discuss all the issues with authority. But most of all, it requires that the hearing examiner himself be completely prepared; that he has read and considered everything applicable to the particular hearing, and that he be in a position to ask the right questions to force the attorneys to concede that which they know they must eventually concede, and so that any discovery which is to be conducted can be properly controlled.

To see to it that the examiner is so prepared, it will be necessary for the FDA to appoint the examiner to a particular hearing as far in advance as possible and that he be given specific instructions to conduct meaningful pre-hearing conferences. The FDA will have to grant him the authority to cull out, at the pre-hearing conference, repetitious exhibits, repetitious testimony where that is indicated, and to require admissions of facts from attorneys, even attorneys for the FDA.

It has also been suggested that when discovery appears to be necessary after such a pre-hearing conference, that it be provided for.[3] In this connection, I believe that under current statutory law it is possible for the examiner to supervise and require the answering of requests for admissions and to provide for the use of depositions, all with the twin goals in mind of eliminating surprise and narrowing the issues which actually have to be heard in open hearing. To do this it will be necessary for the agency to recognize that the examiner has the authority to exclude from the hearing any party or witness who fails to abide by his orders regarding such discovery, even if they be FDA witnesses. And there is no reason why even a giant case, such as the vitamin hearing, could not utilize these same discovery tools. For instance, while no one would want his expert witness to be deposed 110 times by 110 participants in a hearing, it should be possible for the examiner to provide for one attorney to depose the witness, and if there are any further questions which other attorneys believe necessary, they would have to show good cause to the examiner why they should be asked. This time-saving procedure was used in the electrical antitrust cases where the attorneys for the multiple plaintiffs and defendants rotated the taking of depositions so that each deponent was only deposed once, with additional questions being permitted only in rare circumstances.

[3] Kintner, "Discovery in Administrative Adjudicatory Proceedings," 16 *Administrative Law Review* 233 (1964).

Conference Conduct

At the pre-hearing conference, the examiner should be sufficiently prepared on the issues so that he can require the parties to disclose those fact issues which are really in dispute. This would be a major improvement over the current situation, where the issues are stated by FDA and are usually couched in such statutory language as to be useless.

As for the hearing itself, the responsibility for its expeditious conduct rests upon the hearing examiner in the first instance, but also upon all the attorneys appearing. For some reason, attorneys at administrative hearings do not act as they do in court. There is too much wrangling between opposing counsel; there is a lack of decorum; and there is a failure to recognize the means by which evidence is properly presented. I refer to the tendency of attorneys to get up and ask questions or speak whenever they feel like it. All of us should take it upon ourselves to discipline ourselves in this regard, and I am only casting the first stone because I've got the rock in my hand; not because I have not sinned. We must avoid repetition even if it means that on occasion our clients will not read in the record the wonderful and trenchant comments which we made that day.

If we will do this, then the burden on the hearing examiner in conducting a proper hearing will be much easier. He still has the burden of eliminating repetitious direct and cross-examination and, here again, the agency must support the examiner so that he knows he has the authority to properly control these hearings. This means, naturally, that FDA counsel must take the lead in these matters. They themselves must be sure that they do not offer repetitive testimony and they must help the examiner to see that no one else does. As one author put it, in commenting on the problem of repetition in administrative hearings: "In general, the Federal Judge is likely to have a greater arrogance than the hearing examiner and considerably less patience with counsel."[4] There is no reason why the examiner could not borrow this leaf from the judge's book. We need that here. In these hearings we are making a record—we are not impressing a jury, and I am quite confident that we do not impress each other.

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[4] Gardner, see footnote 1, page 12.

Jencks Concept

Another technique that can improve both the fairness and expeditiousness of hearings would be the adoption of rules to govern the so-called *Jencks* concept. I believe that when a government witness takes the stand and testifies under oath, all of his pre-hearing written statements and memorandums of interviews should be made available to the opposing parties under proper control by the examiner. If you are not willing to present this documentary background for a witness's testimony, you are not entitled to present the witness at all. There is now ample authority for extending the *Jencks* doctrine to all administrative hearings to require that when a government witness is placed on the stand to testify about certain facts, and it is shown that this witness has prepared prior written reports about these facts, then the government should be required to produce all such documents, subject to proper safeguards. The reasoning behind this is simple and well-stated in brief terms in the *Communist Party* case: "We think [that] simple justice, [and] the fundamentals of fair play require no less."[5] Other agencies such as the National Labor Relations Board, the Civil Aeronautics Board and the Federal Trade Commission have done it, and it can properly be done here so as to bring both this element of fair play to all FDA hearings and, if good safeguards are written in the regulations, to protect the government's obligation regarding confidential documents.[6]

Other suggestions not related directly to the conduct of the actual hearing are also being considered. These include more precise guidelines governing *ex parte* communications, the question of whether the examiner should file an initial decision, and the question of whether any steps are needed in order to assure the complete independence of the hearing examiners. **[The End]**

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[5] *Communist Party of U. S. v. S. A. C. B.*, 254 F 2d 314, 328 (C. A. D. C., 1958).

[6] (CAB) *Great Lakes Airlines v. CAB*, 291 F 2d 354 (9th Cir., 1961) cert. den. 368 U. S. 890; (FTC) Ernst Mark High, 56 FTC 625 (1959); L. G. Balfour Company, FTC Docket #8435 (1965-1967 Transfer Binder) Trade Reg. Rep. ¶ 17,532 (1966); and Inter-State Builders, Inc., FTC Docket #8624 (1965-1967 Transfer Binder) Trade Reg. Rep. ¶ 17,532; and, see Alleyne, *The Jencks Rule in NLRB Proceedings*, 9 Boston College Corporation and Industrial Law Review 891 (1968); for the NLRB regulation see 29 C. F. R. 102.118 (1968) as amended by 33 Fed. Reg. 9819 (July 9, 1968).

Regulations— The Industry View

By EDWARD BROWN WILLIAMS

The Two Following Articles Were Presented at the Boston Food Update Conference of the Food and Drug Law Institute on February 9, 1969. Edward Brown Williams, of Washington, D. C., Is a Former Principal Attorney of the FDA.

DESPITE THE SUBJECT OF THIS PAPER—"The Industry View"—I should like to enter the disclaimer that I represent no position but my own. I suspect, however, that some of the views which I shall express are rather widely held in industry.

As a sort of preamble, I should like to delineate my concept of the respective positions in the regulatory area of a government agency and the regulated industry and its members. One of the subjected to criminal penalties under a statute such as the Federal, most significant aspects of the position of a government regulatory agency, as contrasted with that of the regulated industry and its members, is that if the government makes a mistake, the industry or its members suffer but the government does not, and, if the industry or a member makes a mistake, exactly the same result follows—the industry or member suffers and the government does not.

These are facts of life in the regulated industries. They place the responsible government employee in an enviable position indeed, as contrasted with the vulnerability of responsible employees of industry. Industry employees, as well as their corporations, may be subjected to criminal penalties under a statute such as the Federal Food, Drug and Cosmetic Act.

I make the point because to me it is an elementary principle of fairness that government should use an exceedingly high degree of care in imposing regulations upon industry, the violation of which may, if the regulations are valid, result in the imposition of criminal penalties, whereas, if the regulation exceeds the authority of the agency or is invalid for some other reason, the agency and its employees suffer nothing except, perhaps, disappointment. A regula-

tory agency has no more important duty than that of writing and pursuing policies which are concise, understandable, and within the law. Listed here are a few examples of regulations and policies which I think clearly fail to meet such a standard. The examples are from activities of the Food and Drug Administration (FDA), because those activities are foremost in my mind right now, not because that agency is regarded as the sole offender.

FDA "Philosophy"

The basic training manual of FDA for beginning inspectors lists, as basic policy objectives, the protection of the health and welfare of the consumer and the protection of the honest manufacturer from his unscrupulous competitor. It also states in part, that: "This policy embraces the philosophy, first of all, that the consumer and the regulated industries are entitled to know what the laws mean . . ."[1]

This "philosophy" meshes nicely with fundamental concepts of fairness and with the constitutional principle that the law "must adequately inform those who are subject to . . . [it] what conduct will be considered evasive so as to bring the criminal penalties of the act into operation . . . the elements of evasive conduct should be so clearly expressed . . . that the ordinary person can know in advance how to avoid an unlawful course of action."[2]

It has been noted that the Federal Food, Drug and Cosmetic Act is a criminal statute and that responsible employees of corporations can be subjected to criminal penalties. This may include fines and imprisonment. Moreover, liability for violations attaches even though there is no awareness of wrongdoing by the accused. It cannot be over-emphasized, therefore, that the regulation of an industry under a liability-without-fault statute like the Federal Food, Drug and Cosmetic Act, places upon the regulators and the courts a heavy obligation, as a matter of fairness alone and without regard to the constitutional requirement that industry be fully informed of "what the laws mean."

In all candor it should be recognized that the FDA, for many years, has fully participated in some and initiated other FDA-industry activities designed in substantial part to acquaint industry with FDA's view of the law and the meaning of its regulations. This we applaud and for it we are grateful.

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[1] Barnard, "The Regulator and the Regulated," 23 FOOD DRUG COSMETIC LAW JOURNAL (December, 1968).

[2] *M. Kraus & Bros. Inc. v. United States*, 327 U. S. 614, 621-622 (1946).

The reverse side of the coin presents a less agreeable picture. Here are some examples of it.

"Mandatory" or "Directory"

FDA has recently republished a proposal for Good Manufacturing Practice (GMP) regulations in the Federal Register of December 20, 1968 (33 Fed. Reg. 19023). The proposed regulations are based upon Section 402(a)(4) of the Food, Drug and Cosmetic Act, under which a food is misbranded if it is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth. It is stated in the proposal, with respect to the so-called "standards of sanitary food processing" therein provided that: "Some of these standards are set forth in mandatory terms; others are directory. All should be observed to satisfy the requirements of current good sanitation practice in food processing and holding." The "mandatory" provisions are phrased in terms of "shall." The so-called "directory" provisions are in terms of "should."

The word "directory" has various applications. Its meaning in the GMP proposals is not stated. Perhaps it is intended to have the meaning illustrated by Section 305 of the Food, Drug and Cosmetic Act. That section provides—

> Before any violation of this Act is reported by the Secretary to any United States Attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

This means, according to the Supreme Court, that the Secretary does not have to do what the statute directs him to do, that is, he does not have to give a prospective defendant notice and an opportunity to present his views, as the statute directs.[3]

It is obvious that failure of the Secretary to obey the direction of Section 305 would not result in any sanction being invoked against him, even if the Supreme Court had not spoken, since no such sanction is available. It is not so obvious that the failure of a member of the food industry to comply with so-called "directory" provisions of the proposed GMP's relating to sanitation would not result in a civil or criminal proceeding against the company or its product and, perhaps, against a responsible individual of the company.

The proposal[4] provides in part that "all reasonable precautions, including the following, should be taken to assure that production

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[3] *United States v. Dotterweich*, 320 U. S. 277, 64 S. Ct. 134 (1943).

[4] Section 128.7.

procedures do not contribute contamination . . . to the finished product:" Then follow paragraphs (a) through (j) of that section which purport predominately to be mandatory or "shall" provisions relating to conditions of storage, requirements of washing and cleaning, cleanliness of ice used, maintenance of processing equipment, and some "should" provisions concerning such matters as inspection of containers of raw ingredients and conditions of processing to avoid bacterial growth.

Thus, a spate of both "mandatory" and "directory" provisions is injected into Section 128.7, following the "directory" sentence of which they purport to be examples.

Given such a format, not even an expert, much less a small businessman who cannot afford to turn to an expert for a judgment of the liability of his every move, can "know what the laws [in this case the regulations] mean." This puzzlement is certainly not dissipated by the statement in the current proposal that all the standards set forth in the proposal, including the so-called "directory" ones should be observed "to satisfy the requirements of current good sanitation practice in food processing and holding." If it is advisable to comply with the "should" or "directory" provisions in order to obtain good sanitation and prevent contamination, a failure to do so appears to invite a charge that the food was prepared or held under insanitary conditions in violation of Section 402(a)(4) of the statute—the very provision upon which the so-called "mandatory" provisions are based.

This sets one to wondering just what the purpose was, in such a situation as that which I have outlined, in setting up an apparent dichotomy between "mandatory" and "directory" provisions. The term "directory" is ill-chosen, and in the case of some of the proposed provisions, there has been a failure, by a substantial margin, to satisfy the FDA's expressed philosophy of telling industry "what the laws mean."

Crepe Labels

Other examples of the failure to tell what the law means, or its effect, are available in the proposed GMP's. But let me pass to the proposed order relating to foods for special dietary use, which is now the subject of what has been referred to as a monstrous administrative proceeding because it involves more than a hundred formal participants, an unconscionable number of lawyers, the life or death of industries, and uncounted millions of dollars worth of vitamins and minerals and the foods in which they are incorporated

or to which they may be added; and it is truly a marathon proceeding, having been under way since May, 1968 and promising to be with us for one to two years in the future.[5]

It might be thought that clarity of purpose and a clear exposition of the meaning of the regulations would have been incorporated in such an important document as this one. Instead we find that provisions which have the force and effect of law when legally adopted by the agency (that is, their violation is itself a violation of the statute) are commingled in the regulations with provisions which are interpretative only, in that their violation is not a violation of the statute unless a violation of the statute itself is actually shown to the satisfaction of the court.

Thus, the regulations purport to require in Section 80.1(f) that the label of each dietary supplement bear the following statement:

> Vitamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.

This is the "crepe label." Aside from its vagueness and the question of its accuracy, this provision appears in a section of the proposal (Section 80.1) which purports to establish definitions and standards of identity for dietary supplements. Such standards, if legally adopted, have the force of law, and failure of a dietary supplement to conform with such a standard would subject the shipper of the article to the criminal penalties of the statute. The statement quoted does not have the force and effect of law, and the validity of the requirement that it appear on the label would have to be established in a court of law in order to punish the shipper of the supplement. Yet there is no indication on the face of the regulation itself that whatever authority there is for it is not derived from the same provision as that relied upon for the standards for dietary supplements. Here again I have cited only one example, of which there are many, of the failure of the agency to achieve clear and understandable regulations.

Drug or Device?

As a final example I shall deal briefly with the recent case of *AMP, Inc.*[6] In that proceeding the United States Court of Appeals for the Second Circuit held that under the Food, Drug and Cosmetic

[5] The Order is technically stayed pending current public hearings on its provisions. The text is found at 31 Fed. Reg. 15730 and following.

[6] *AMP Incorporated v. Gardner*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,192 389 F. 2d 825 (CA-2, 1968); cert. denied, U. S. Sup. Ct., under the name *AMP, Inc. v. Cohen*, 89 S. Ct. 86 (1968). A petition for rehearing is pending (as of February 6, 1969).

Act, certain suture products used for ligating or tying blood vessels during surgical procedures were "drugs" and not "devices" as contended by AMP. The court relied primarily on the theory that the distinction in the statute between "drug" and "device," for which there are separate definitions,[7] was not considered very important by Congress; that the purpose of Congress in enacting the new drug provisions of the Act[8] was to keep out of interstate commerce inadequately tested medical and what it referred to as "related" products, which might cause widespread danger to human life; and that, since this purpose could only be achieved by classifying the AMP products as drugs, they would be so classified. The court also noted that "AMP's ligatures are of nylon suture material of the type recognized in the United States Pharmacopeia,[9] and such suture material has always been regarded as 'drugs' by the Food and Drug Administration" (389 F. 2d at 830).[10] Instead of relying on this narrow ground, which would have been defensible, the court in effect obliterated the distinction between "drugs" and "devices" except for apparatus such as diagnostic machines referred to in the legislative record.

The District Court, whose decision was affirmed by the Court of Appeals, had even gone so far as to state that—

> Assuming *arguendo* that the products fit within both definitions,[11] the remedial nature of the Food, Drug and Cosmetic Act warrants a liberal construction for the protection of the public health and, thus, a finding that plaintiff's products are drugs

and—

> The public will be better protected by classifying plaintiff's products as drugs rather than devices so that proper testing, controlled by he government, can be pursued.[12]

The Government can use such a "remedial purpose" concept as a basic argument to pull under the coverage of "drug" perhaps thousands of articles which have never been regulated as drugs, such as chemicals used in laboratory procedures and other laboratory testing materials. The Government says that the courts should apply the Act "functionally" to afford the public the protections of the statute.

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[7] Sections 201(g) and (h).

[8] Section 505.

[9] 691 (17th revised edition, 1965).

[10] 389 F. 2d at 830. The court added, in a footnote: "As the District Court noted, the exclusion clause of Section 201(g) of the Act [excluding devices from the definition of 'drug'] prevents listing in the Pharmacopeia from being conclusive on the classification issue." This approach ignores the fact that if a substance is "recognized" in the Pharmacopeia it is a "drug" under the statutory definition.

[11] This assumption is directly contrary to the express exception of "device" from "drug."

[12] 275 F. Supp. 410, 414 (DC NY, 1967).

It may occur to some that if these protections are needed, the Government might ask Congress to give it explicit authority to provide them. Instead it seeks in effect to develop a judicial rule that would result in the application of the definition of "drug" to any article which, in the opinion of the FDA, should be subjected to its detailed supervision and control under the statutory requirements relating to drugs, new drugs and antibiotic drugs.

By thus in effect destroying the distinction between "drugs" and "devices," despite the clear statutory dichotomy, the government may, indeed, in some cases increase the protection of the public. In most, however, it will have done little, if anything, constructive except to impose the heavy hand of bureaucracy upon another industry.

It will have accomplished something worse than that. It will have made it next-to-impossible, in the language of the Supreme Court, "for the ordinary person to know in advance how to avoid an unlawful course of action" because the classification of an article is based, not upon law, but upon how FDA wants to regulate it.

Conclusion

It would be more consistent with our legal and constitutional traditions for the government to give some attention to the plight of the businessman who is faced with the necessity of guessing whether the courts will say, for example, that a particular article should, in the interest of the public, be treated as a drug despite the fact that it falls within the category of an instrument, apparatus, or contrivance, and is not recognized as a drug in an official compendium—the United States Pharmacopeia or the National Formulary—or the necessity of guessing what the courts will say about the classification of articles which have, for many years, been regulated as devices but now are regarded by the FDA as drugs because of the *AMP* decision.

A regulatory agency such as the FDA is not without its own problems and tribulations; and too often industry is slow to recognize the need for improvement in its own performance, thus inviting the imposition of regulatory measures by government. Nevertheless, when such measures are imposed we must insist, to the full extent of feasibility, that they be reasonable and understandable. The stakes are too great to do otherwise.

Long ago it was written that "The law is a hocus-pocus science."[13] It need not be all that bad. **[The End]**

[13] Macklin, Charles (1690-1797) "Love a la Mode," Act II, Scene 1.

The Food and Drug Administration and Nutrition

By VINCENT A. KLEINFELD

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THE DESIRE OF THE STATE to protect the consumer from the adulteration and misbranding of foods can be traced back virtually to the beginning of recorded history. Athens and Rome enacted laws to prevent abuses. In France and Germany, food control laws were enacted in the Thirteenth Century, and in 1266 a statute was passed in England requiring bakers to mark each loaf so that if a bad one turned up "it will be knowne in whom the faulte lies." Flemish innkeepers who sold unmarked breads were sometimes hanged, and thus treated almost as severely as some of our officials wish to handle present day offenders.

No one can contend, with any semblance of reason, that there must not be strong regulation of the production and marketing of foods. Certainly in this field the consumer must be protected. This is true not only because foods so vitally affect health and well being, but also because the food field traditionally appealed in the past to the dishonest and unscrupulous entrepreneur looking for an easy way to make his fortune.

The enactment of federal legislation in the United States has always been the result of long, drawn out congressional struggles. It is only after serious abuses have arisen and public opinion strongly aroused that legislation becomes possible. It may be said, parenthetically, that although the legislation that comes to pass is traditionally a compromise between those who wish extreme and unnecessary regulation and those who desire practically no effective controls, the construction given to the laws by the Food and Drug Administration (FDA) and ordinarily accepted by the courts often obliterates these compromises.

Pure Food and Drug Act of 1906

It was the muckrakers in the early part of this century who revealed the flagrant abuses existing in the United States in the marketing of foods and drugs. Their articles in magazines such as *The Ladies Home Journal* and *Collier's Weekly* helped create a strong public ferment for legislation. As a result, President Theodore Roosevelt recommended to Congress "that a law be enacted to regulate interstate commerce in misbranded and adulterated foods, drinks, and drugs. Such law would protect legitimate manufacture and commerce, and would tend to secure the health and welfare of the consuming public." The resultant enactment of the first national statute, the Pure Food and Drugs Act of 1906, after extended and controversial debates and hearings, was a long step forward in consumer protection and in aiding the legitimate manufacturer to resist the pressures of his marginal and unscrupulous competitor. Certainly the food and drug industry did not suffer from passage of the law, despite the contention by many that the law was unnecessary, socialistic, and an unconstitutional invasion of the right of the states to legislate in the field of foods and drugs.

It was realized, not long after the passage of the 1906 statute, that there were a number of serious inadequacies. For example, there was nothing in the law directed against the use of slack fill containers. The "distinctive name" provision made it very difficult to proceed against trade-marked food products. The FDA was not authorized to promulgate definitions and standards of identity for foods. There was no provision for inspections, and the penalties for violations were such that they amounted to "license fees" to violate the law.

These serious defects were magnified by the economic and social changes which had taken and were taking place. Millions of persons were moving to the cities. The number of manufacturers of food increased tremendously as did the value of their products. As a result of decisions of the Supreme Court preventing control, by a manufacturer, of the resale prices of those of his products which were covered by a patent or trademark, there was an increase in competition which in turn had an effect on the administration and enforcement of the 1906 Act. This was due to the fact that that law was designed to affect the pocketbook as well as the health of the consumer, and as competition grew increasingly bitter there were concomitant efforts by some in industry to cut economic corners.

Federal Food, Drug and Cosmetic Act

It was finally realized that amendments to the 1906 law would not suffice and that an entirely new and broader statute was needed. After five years of legislative strife, the Federal Food, Drug and Cosmetic Act was passed in 1938. Although, of course, the usual compromises had been made, it was a broad and comprehensive statute. It met most of the problems which had disclosed themselves subsequent to the passage of the prior law. The provisions bearing on the adulteration and misbranding of foods were tightened, and economic adulteration was forbidden. Factory inspection was authorized. The "distinctive name" loophole was shut; special provision was made with regard to foods purporting to be or represented for special dietary uses; slack-filling was made a specific offense; and section 401 authorized the Secretary to promulgate regulations establishing, for almost any food, a reasonable definition and standards of identity, a reasonable standard of quality, and reasonable standards of fill of container. The use of the word "reasonable" is to be noted.

The food industry can take real credit for its part in stimulating research in food technology and nutrition. There is no question but that this research has caused an improvement in the health and nutritional status of millions. But the consumer is not qualified to determine the quality of foods in the marketplace, and industry, as well as the public, is aided by firm, reasonable legislation, administered by reasonable men, which gives the consumer the reasonable protection which he requires.

A major task of the FDA should be to engross itself in the field of nutrition, to do what it can to assist in assuring and advising the population of this country of the appropriate foods for a nutritionally sound and balanced diet. Yet, there is no point in unnecessary or unreasonable restrictions or in basing regulations on unproven assumptions with respect to which the scientific community differs, even though government attorneys or enforcement officials have strong personal views on nutritional problems and how to meet them.

One of the problems which most concerned Congress during its consideration of the Federal Food, Drug and Cosmetic Act was that which dealt with definitions and standards of identity for foods. There is no question but that the marketing of inferior products purporting to be superior commodities was a substantial evil. A classic example was a product sold as "Bred Spread," a highly inferior jam in which considerable water had been substituted for fruit.

The result was the inclusion in the 1938 Act of Section 401, authorizing the Secretary to establish definitions and standards of

identity for foods whenever, in his judgment, this would promote honesty and fair dealing in the interest of consumers. As stated, the only legal criterion was that any standard was required to be "reasonable." Have standards which have recently been established been "reasonable"? Have nutrition and the consumers' interest been furthered by various governmental actions? Some of the positions taken in the fairly recent past appear to be in accord with the philosophy of some of those now in our universities that "I'm right and you're wrong, and you can't talk because you're wrong."

Government Attitudes

For example, for approximately ten years the FDA has declared that a truthful and accurate representation of the amount of polyunsaturated fats in a product may not be set forth on the label of a food. The attitude of the government was that the mere mention of the fact that a food product contained polyunsaturates was equivalent to a representation that the product was being offered to reduce cholesterol and aid in the prevention of a heart attack. It appears to me that this had no underlying scientific basis. Perhaps it will be finally determined that the effect of a diet rich in polyunsaturates has no relationship to cholesterol and heart attacks. But certainly many in the scientific professions believed that there was at least a possible cause and effect relationship. The government's position prevented those portions of the population who wished to consume foods rich in polyunsaturates from purchasing them in the marketplace, for industry meekly acquiesced in a governmental pronouncement of dubious legal validity.

Now, at long last, the government may change its position, apparently in part because of the release of a statement by the American Heart Association calling on the government to permit the labels of vegetable oil products to set forth accurately the levels of polyunsaturated fats so that the consumer, frequently on the advice of his physician, may or may not choose to purchase particular food products containing these ingredients. In connection with this situation, we can employ the statement of criticism supposed to have been made by one of Napoleon's ministers, to the effect that something which had been done "was worse than a crime; it was a blunder."

Let us consider another step taken by the government in the field of nutrition. As you are probably aware, there is a definition and standard of identity for margarine which requires a fat content of not less than 80 percent. The FDA took the firm position, in

speeches and otherwise, that under no conditions could a margarine-type product be marketed if, notwithstanding a truthful and accurate statement of the ingredients, the food contained less than 80 percent of fat. Although the Act authorized the sale of imitation foods, the government declared that even a product labeled as "imitation margarine" would be an illegal commodity if it did not conform in all respects to the definition and standard of identity for margarine.

There must have been some great evil thought to be present in such a product, although I have not as yet been able to determine what it was. In any event, the food industry, as is frequently the situation, meekly genuflected until one brave company refused to go to Canosa and make humble submission to the government. Although warned by its counsel that the dreadful specter of regulatory action would probably arise, the company accepted the opinion that such a food was legal and produced and marketed it. The FDA did make a seizure, which was ultimately resolved in favor of the manufacturer. Presumably the government, at that point, realized that the position taken by it was a somewhat peculiar one, not only from a legal viewpoint but also from the viewpoint of many thousands of persons who wanted to be able to purchase a product that organoleptically was virtually identical with standardized margarine and possessed the same general benefits, but which was specifically formulated so that it contained half the fat and half the calories of the standardized food. For the government determined not to appeal the decision to a higher court. As with respect to the polyunsaturates position of the FDA, the query can be raised whether the stand taken by the government contributed to the nutritional status and best interests of the consumer.

There is no question but that the standardization program of the FDA, after the passage of the 1938 Act, was a real aid in bettering the nutritional status of the population of the United States. This program, together with the programs of other agencies and advice from scientific organizations, resulted in the elimination, to a very considerable extent, of frank nutritional deficiency diseases such as scurvy, pellagra, and beriberi. But somewhere along the line, as the years passed, the requirement of the Act that a food be defined and standardized when this will promote honesty and fair dealing in the interest of consumers, and the statutory criterion of reasonableness, seem to have been lost sight of.

Does it make any sense to operate under a procedure which requires the expenditure of hundreds of thousands of dollars and many months

of time on the part of government and industry to determine whether there shall be 87% or 90% of peanuts in peanut butter? The question is particularly pertinent since some of the nation's leading nutritionists testified, without contradiction, that it made no difference, from a nutritional viewpoint, where there is 90%, 85%, or 80% of peanuts in the product. Yet, in the decision reached by the government, there was not even a mention of this fact.

What can be done to remedy this situation, to place the standard-making authority back in the high esteem it once possessed? First, there should be an eagerness on the part of the government to discuss the provisions of a proposed standard informally but extensively with consumer organizations, scientific bodies, other interested federal agencies, and industry. There should be no reluctance to publish proposals for the purpose of obtaining the views, comments and recommendations of all interested parties before issuing a final regulation. After the issuance of a proposal and the passage of many years, perhaps the government should realize that it makes sense, under those circumstances, to issue another proposal in order to secure contemporary recommendations.

Another possible step should be carefully considered. As you are aware, a procedure was recently devised by the FDA pursuant to which drugs which had received new drug clearance prior to 1962 were referred, for opinions on efficacy, to committees established by the National Academy of Sciences-National Research Council. This was a highly constructive step which should at least be given consideration in the establishment of food standards. Why shouldn't the FDA, when it issues a proposal to define and standardize a food, seek the advice and recommendations of the Food and Nutrition Board of the National Research Council, the Council on Foods and Nutrition of the American Medical Association, and other highly reputable and authoritative scientific bodies?

Hearings on Nutrition

Peculiarly enough, even though in the special dietary foods regulations now being thrashed out at the hearings which have taken, and from present appearances will continue to take, an inordinate period of time and require the expenditure of hundreds of thousands of dollars, the FDA adopted the "Statement of General Policy in Regard to the Addition of Specific Nutrients to Foods" adopted jointly by the American Medical Association Council on Foods and Nutrition and the Food and Nutrition Board of the National Re-

search Council, the proposed regulations were never forwarded to those organizations by the government for comments, suggestions or recommendations. Yet the FDA apparently felt so strongly about the importance of positions taken by these bodies that one section of the special dietary foods regulations specifically provides that no amendment for the addition of specific nutrients to food adopted in the regulations shall be permitted that is not in accord with the Statement of General Policy. Can anyone maintain that the transmittal to such bodies, and perhaps to other prestigious organizations devoted to and interested in the field of nutrition, could be or would be a disservice to the consumer? It appears, furthermore, that the government should produce, in vitally important fact-finding hearings involving nutrition, the top scientists of the agency to testify and not rely on subordinate officials. Experts in other agencies in the government should be encouraged rather than discouraged to testify.

In connection with hearings and their aftermath, several steps should be given consideration. It would be advisable to place all examiners who are to conduct standards hearings in the Office of the Secretary of Health, Education, and Welfare rather than in the Office of the Commissioner of Food and Drugs, and these examiners should preside at all hearings of any bureau of that department, including the FDA. It would be advisable to have the Secretary or an assistant secretary of the department, rather than the Commissioner, issue the final regulations. It should be made abundantly clear, also, that those zealous, sometimes over-zealous, officials of the government who participate in and testify at the hearings have nothing whatever to do with respect to the reaching of decisions.

Law and the Government

A different philosophy should be inculcated into those officials of the government, particularly enforcement officials, who are put in charge of the preparation of standards and presenting the government's position at standards hearings. It should be made abundantly clear to these officials that such a hearing was designed by Congress to be fact-finding and not adversary in nature, and that they are representatives of the United States and not of an ordinary client. Not long ago, an eminent scientist was approached by the government with regard to the possibility of his testifying at a hearing. When the government learned that he was vigorously opposed to some provisions of the regulations, it determined not to request him to testify. When industry representatives raised the point at the

hearing, the government officials chuckled merrily at the absurd thought, to them, that a leading expert opposed to some positions taken by the government should be asked to testify.

I do not find this humorous or proper. I am old-fashioned enough to believe that, particularly in a fact-finding hearing which will result in regulations having the force and effect of law which will affect every person in this nation, it is the duty of the agency involved to present all the facts, the entire picture, all the important scientific data. How can an agency of the United States justify the following procedure? The government places a scientist on the stand and examines him with regard to only one section of these regulations or on several specific subsections of a particular section. The government then refuses to permit the expert, chosen by it, to testify on another section or even on the subsection it has studiously avoided in its examination of the scientist, apparently because in some particular he is of an opinion contrary to the government's. Is this an appropriate method of conducting a fact-finding hearing or ascertaining scientific truth?

It may be maintained that those people who wear horns, lawyers, are to be blamed for the inordinate length of time which hearings now take. Many scientists may feel that they should not be subjected to cross-examination. I cannot agree, and I must say that a scientist who is qualified and prepared (and who does not go off half-cocked or engage in evasions or half-truths) need not fear any lawyer.

In any event, the reduction in the esteem in which standards were formerly held is not due in any appreciable amount to the industry lawyer. Certainly it is not his client who determines to spend hundreds of thousands of dollars on peanuts, or publishes regulations which, by their very nature and scope, must necessarily take years before conclusions are reached. It is not he who prepares regulations which are strongly opposed by leading scientific authorities in the field of nutrition. It is not the industry lawyer who goes forward with regulations of tremendous significance to the entire population of the country, as well as to industry, even though important studies and surveys are being presently conducted, the results of which will undoubtedly be of substantial importance with respect to what standards shall ultimately be adopted, because "it's time to get something started." It is not he who produces experts at hearings who proffer nutritional gems of scientific lore such as the following, offered by a pharmacologist (I do not employ the word "nutritionist") attempting in every possible and adroit way to support every contention made by the government:

Q. Then would it be your opinion that the average layman is eating a well-balanced diet from the foods commonly available supplying the nutriments?

A. Yes, just for the same reason that for centuries, from the time man appeared on earth, he seemed to get along without much knowledge, long before nutrition, vitamins, other sciences were discovered. There is a natural, instinctive force that drives the individual. I said their knowledge[of "the average American housewife"] was poor, they would not pass an examination that I could give on the basic principles of nutrition. That still gives them sense enough when they go into the grocery to know from taste, as their ancestors for centuries and millenia have done, to get proper foods.[1]

Q. Are you saying that since man has lived on the face of the earth for many thousands of years he must have eaten adequate diets in that period?

* * *

A. Certainly adequate for his survival.

Q. For how long, Doctor?

A. Well, depending upon your theory as regards how long man has been on earth. Certainly for, I think—I think all would agree it has been a long period, during which time he was able to keep in sufficiently good state to reproduce and survive. I think that is evidence that he got what he needed in the way of nutrition.

My final recommendation would be that the Secretary appoint an ad hoc committee composed of representatives of the foremost scientific bodies of the nation and of the FDA, Public Health Service, and Department of Agriculture, together with consumer representatives and leading experts in administrative law, to go into the entire problem of standard making. This committee would make recommendations to the Secretary and perhaps to Congress for the purpose of streamlining the procedures to be pursued in connection with the promulgation of regulations defining and standardizing foods.

[The End]

[1] In "Facts About Nutrition", published by the Public Health Service, U. S. Department of Health, Education, and Welfare, (Public Health Service Publication No. 917), the following statement is made: "The lower forms of life are guided by instinct in their selection of the 'right' foods—those which contain all essential nutrients. The food choice of civilized man, however, is not based on instinct. It is influenced by many other factors, such as background, habit, taste preference, susceptibility to advertising, family finances, economic situation, and many others."

FOOD DRUG COSMETIC
LAW JOURNAL

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