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Food Drug Cosmetic Law JOURNAL

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

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Similarities of and Differences Between the Food Laws of France and the United States.—*J. P. K. van der Steur,* a member of the Food Law Advisory Committee, nominated by the Queen of the Netherlands, and an advisor to the council of Dutch Employers Organization for Food Law Problems, discusses the food laws of France and the United States, concentrating on the areas of food additives and regulatory departments. The article, which commences on page 386, was translated by Ann M. Wolf.

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"Cosmetic" or "Drug"— The Minotaur's Labyrinth

By VINCENT A. KLEINFELD

This Paper Was Presented at the Semi-Annual Scientific Meeting of the Society of Cosmetic Chemists in New York City in May, 1967. Mr. Kleinfeld Is a Member of the District of Columbia Bar Association.

I ASSUME THAT MOST OF US are generally familiar with the provisions of the Federal Food, Drug and Cosmetic Act dealing with cosmetics. A brief resume, however, may be helpful in refreshing our recollection. A cosmetic is misbranded, as are the other categories of products covered by the statute, if its labeling is false or misleading in any particular and unless its label sets forth the name and place of business of the manufacturer, packer or distributor and an accurate statement of the quantity of the contents. Any information required by the Act to appear on the label or labeling must appear prominently, and with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The container of a cosmetic must not be so made, formed or filled as to be misleading. The Secretary is authorized to promulgate regulations exempting from the labeling requirements of the statute cosmetics which, in accordance with trade practice, are to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on the condition that the cosmetics are not adulterated or misbranded when they are removed from the processing, labeling or repacking establishment.

A cosmetic is adulterated if it contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use set forth in the labeling or under customary or usual conditions. There is a specific exception, however, with respect to coal-tar hair dyes. If these dyes bear or contain any such poisonous or deleterious substance, they may still be marketed if the label bears a caution, which must be "conspicuously displayed," that the product may cause skin irritation on certain individuals and that a preliminary test of the product should first be made, and directing that the product must not be used for dyeing the eyelashes or eyebrows—"to do so may cause blindness." The labeling (not necessarily the label) must contain adequate directions for the testing. (It is important to realize that the term "hair dye" does not include eyelash or eyebrow dyes.) It may be noted that, throughout the years since the passage of the Federal Food, Drug and Cosmetic Act in 1938, many in the cosmetic industry have been of the opinion, a firm but erroneous one, that the label of every coal-tar hair dye must contain the caution statement to which I have adverted. This is not so. A careful reading of the applicable section (601(a)) will reveal that the requirement is directed to a coal-tar hair dye which contains a poisonous or deleterious substance which may render the product injurious to consumers.

A cosmetic is also deemed to be adulterated, again as in the case of drugs and foods, if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it has been prepared, packed or held under insanitary conditions, or if its container is composed of any poisonous or deleterious substance which may render the product injurious to health.

The Color Additive Amendments of 1960 added new and important provisions to the Act with respect to color additives, and the Act provides, in part, that a cosmetic is violative of the law if it is not a hair dye and it is or contains an unapproved color additive. Inasmuch as the Color Additive Amendments are not in reality being enforced because the applicable regulations of the Food and Drug Administration (FDA) have been attacked in the courts, I shall not discuss the Amendments. A study of them and of the applicable legislative history, as well as of the scope and extent of the pertinent regulations issued by the FDA, should make an interesting paper by itself, if only to reveal what an administrative agency, by regulation, can do to and with a law.

Liability of Manufacturer or Distributor

There are two extremely important factors which should cause those in the cosmetic industry to proceed most carefully before marketing a product. A cosmetic manufacturer or distributor may be convicted of having violated the Act regardless of intent, motive, or even consciousness of wrongdoing. The extent of this liability is highlighted by a case which went to a high court a few years ago. The defendant, a distributor of cosmetics, entered into a contract with "H" whereby "H" agreed to manufacture, place in packages, and distribute to defendant's customers hair lacquer pads. The defendant supplied "H" with jars, caps and labels, and "H" impregnated the pads with a shellac lacquer approved by defendant, placed the pads in labeled jars bearing defendant's name, and shipped the packages in accordance with directions furnished by defendant. A sample submitted by "H" was tested by the defendant and found to be satisfactory. Later, without the defendant's knowledge, "H" substituted for the lacquer a gum which resulted in physical damage to a number of women using the pads. The defendant was prosecuted and found criminally liable for having procured the manufacture and distribution in interstate commerce of a deleterious cosmetic. The court of appeals, in affirming the defendant's conviction, held that a person who brings a product covered by the Federal Food, Drug and Cosmetic Act into commerce is bound to see to it that the commodity does not violate the provisions of the statute. The court declared that such a person owes a strong duty to the public, and that if he entrusts its performance to another, whether the other be an independent contractor or agent, he becomes criminally responsible for the failure of the person to whom he has delegated the obligation to comply with the law.

Further, a corporate officer, agent, or employee may personally be prosecuted and convicted for an illegal shipment by the corporation even if he had no direct part in the transaction. He may be held criminally liable merely on the basis of having had a generally responsible share in what took place. This absolute liability is bottomed on the philosophy that, in this most important field of consumer protection, penalties serve as the effective means of regulation, and that for this reason the statute dispenses with the traditional requirement for criminal conduct, awareness of some wrongdoing. This is predicated on the proposition that, in the interest of the larger good, the Act puts the burden of acting at hazard upon a person otherwise in-

nocent but standing in responsible relation to a public danger. This fundamental policy viewpoint is readily understandable, but the hazard upon the manufacturer or distributor is a serious one and must be borne in mind by those who are either in or entering the field of cosmetics.

There is a further significant consideration to be borne in mind with respect to the Federal Food, Drug and Cosmetic Act. The courts have stated repeatedly that the primary purpose of the Act is not to protect dealers and experts but the public, and that in determining whether a product is to be determined to be safe or dangerous, consideration must be given to the fact that it is to be consumed by the strong and weak, old and young, sick and well. It is also important to comprehend that the statute condemns misleading, as well as false, statements, and that its purpose is to prevent deception from indirection or ambiguity. Thus, even if labeling contains no false statement, the product will be violative of law if the labeling creates a misleading impression.

The Act controls the "labeling," but, with the exception of prescription drugs, not the "advertising," of foods, drugs, devices, and cosmetics. Advertising is subject to the jurisdiction of the Federal Trade Commission under the Federal Trade Commission Act, but the line between labeling and advertising is by no means clear-cut. Labeling is defined in the Federal, Food, Drug and Cosmetic Act as all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or "accompanying" the article. Consequently, the interpretation of "accompanying" and "labeling" frequently is determinative of whether printed material referring to an article places the article, and its shipper, within the scope of the Act.

The courts, including the Supreme Court, have broadly construed the terms. The fact that a product is shipped at a different time, does not go over the same route, and is received at a different time from printed material, such as a circular, placard, or leaflet, does not mean that the product was not accompanied by the printed material if there is an interdependent relationship between the material and the product and both had a common origin and ultimately became associated together. For example, in a criminal prosecution, the Supreme Court held that booklets shipped a year and a half after a drug product had "accompanied" the product in interstate commerce, so that the shipper could be convicted for having violated the Act by introducing into

interstate commerce a drug which was misbranded because of false therapeutic claims made for it in the printed material.

Drug or Cosmetic?

It is vital to comprehend the importance of semantics in this field of law. The statute specifically defines "drug" and "cosmetic." A product is not within the scope of the Act at all if it does not fall within one of the definitions. Frequently, a few misguided words may place under the coverage of the Act a commodity which would otherwise be free from its provisions. Similarly, some ill-chosen phraseology may convert into a drug a product which is essentially a cosmetic and which properly should not come within a drug classification. It is the position of the FDA that a preparation may fall into more than one category, depending on its uses or intended uses as revealed in its labeling and advertising.

A face cream is a cosmetic, but becomes a drug if it is sold for the removal of wrinkles and crow's feet resulting from the aging process. A tooth powder comes within the cosmetic category if offered for the purpose of keeping teeth clean and breath fresh. It will also be a drug if its labeling or advertising represents that it will directly reduce the incidence of dental decay. An obvious indication of the difficulty in attempting to determine, with any degree of certainty, what the reaction of the FDA will be to a particular product or category of products, or to particular language, is the regulatory proceedings instituted in the recent past against products offered for the temporary concealment of wrinkles, on the ground that they were drugs and new drugs.

Some of the informal advisory opinions rendered in the past by the FDA with respect to whether a product was a cosmetic or a drug are interesting, although they are not of major assistance in establishing any real guidelines or criteria. It was held that a deodorant was a cosmetic, but became a drug if anti-perspirant claims were made. Depilatories were declared to be cosmetics, although it was "conceivable that such preparations may be represented in such a way as to class them as drugs." Similarly, baby oil was stated to be a cosmetic "unless some claim is made for the article which will classify it as a drug." Camphor ice, marketed for softening the lips, hands, and roughened skin, was held to fall into the cosmetic category. The FDA declared that soap, although exempted by the Act from the definition of a cosmetic, might become a drug if claims which amounted to

therapeutic representations were made on its behalf. Cuticle removers were stated to be subject to the cosmetic provisions of the statute. And preparations offered for sunburn were stated to be drugs (therefore new products of this character may be new drugs), although they are cosmetics if held out for their assistance in permitting mad Americans to obtain a tan.

It is obvious, from a study of these advisory opinions rendered in the past by the FDA, that the legal distinction between what makes a product a drug or a cosmetic is indeed a tenuous one. Generalizations are particularly unsafe, and the only approach which makes any sense at all is one which requires the examination, in each instance, of the product which one intends to market, and particularly of every piece of its promotional material, including its advertising. Every word must be scrutinized.

As a generalization, however, it can be stated that products offered for their moisturizing, astringent, soothing, emollient, and lubricant properties would probably fall into the cosmetic category. Products offered for dryness, and to soften skin, may also, in my opinion, be deemed to be cosmetics. On the other hand, products offered as buffering agents, or for the the relief of itching or scaly skin, or for their antibacterial properties, or as an aid in clearing skin blemishes, or as a protection against environmental factors, including bacteria and chapping, would be considered to be drugs. It can readily be seen that the problem of whether a product is a cosmetic or a drug is a difficult one and one which must be approached with the greatest caution. Not only must the particular claim or representation be carefully examined by itself, but also in context with the remaining language of the promotional material.

In connection with the extremely difficult task of determining, in any instance, whether a product one wishes to market falls within the statutory definitions of a cosmetic or a drug, it is vital to keep in mind that, in the present regulatory Washington climate, there is a growing tendency for the government to denominate everything as a drug and every drug as a new drug. Thus, one extremely important function of the alleged expert in this field, whether he be a chemist, dermatologist, or attorney, is to determine in what instances and under what circumstances should an opinion be requested from the FDA. Further, when one is not certain as to the category into which a product will fall (and this is more the rule than the exception), even greater care should be taken than in other situations to be reason-

ably certain that injuries will not occur. If there are injuries, even after the passage of years, the FDA may suddenly take the position that the product is a drug, and therefore an unapproved new drug, so that it (together with its shipper) violates the statute.

This would indeed appear to be a rather peculiar situation—that a product may be held and determined to be a drug rather than a cosmetic because of the fact that injuries have or have not occurred, particularly since a cosmetic (with certain exceptions with respect to coal-tar hair dyes) also is adulterated if it causes or may cause injury. Nevertheless, it is a fact of life that if a gray-area cosmetic is marketed and causes injury it may, by some governmental legerdemain, be metamorphosed into a drug.

Practical Differences

At this point the question may be asked as to what practical difference it makes whether a product is a drug or a cosmetic, since both fall under the coverage of the Federal Food, Drug and Cosmetic Act. There are vital distinctions, although, these disparities may disappear when (as appears inevitable) a "new cosmetic" amendment of the Act is enacted which will require preclearance of cosmetics by the FDA.

As the law stands now, however, the label of a cosmetic need not contain a listing of its active ingredients or, again with the exception of coal-tar dyes, the kinds of "adequate directions for use" which must be utilized for drugs. These differences, although important, are not vital. The really fundamental distinction is that, as indicated, the law does not provide that "new cosmetics" must obtain the prior approval of the FDA as to safety and, directly or indirectly, of effectiveness. If a drug is a "new drug," however, a new drug application must be filed with the FDA after the expenditure of very considerable amounts of money before the product may be marketed. This approval, if in fact it is ultimately secured, is usually obtained after many, many frustrating months and perhaps years have passed.

As indicated, in practically every instance the FDA declares (if its opinion is requested) that a product which one proposes to place on the market is a "new drug," thus subjecting it to the prior approval of and continuous scrutiny by the FDA. The reason that the FDA can take this usually adamant and unyielding position, even when it seems clear that the product is not a drug at all, let alone a new drug, is the vagueness and ambiguity of the statutory definition of a

drug and new drug. It would be difficult to formulate language which is more vague and general. The Act defines a "drug," in part, as articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopoeia or National Formulary, "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease . . . ," and (this is most important) articles "intended to affect the structure or any function of the body of man . . . ."

A "new drug" is a drug which is not generally recognized, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling, or any drug the composition of which is such that, as a result of investigations to determine its safety and effectiveness for use under such conditions, it has become so recognized but has not been used to a material extent or for a material time under such conditions.

F.D.A.'s Basis for Decisions

I am frequently asked about the bases upon which the FDA reaches a decision that a product falls or does not fall under the definition of a new drug. One basis is a rather infuriating one. As I have indicated, if the question is posed to the FDA whether a preparation is a new drug, you can rest assured that in practically every instance the answer will be in the affirmative. If this is so, then of course the inquirer is stuck with the answer. The government appears to take the view that, if the question is propounded, there must be some doubt and, virtually by definition, the product involved is a new drug. This can hardly be said to be a legal or scientific approach to the problem, but there is no doubt that that situation exists.

It is easy for the government to rationalize this course of conduct. If a commodity is classified as a new drug, tremendous information must be submitted to the government in the form of a new drug application, both with respect to the safety and effectiveness of the product. The data furnished to the government also includes the label and labeling which are to be utilized; and any changes in the label, labeling, or even advertising are subject to great control by the FDA. Further, if a preparation is a new drug, rather than a cosmetic, periodic reports must be made to the FDA with respect to any mix-ups, complaints, injuries and the like. The scope of factory inspection is greatly augmented. Effectiveness of the product must be demonstrated. In this connection, take a look at most of the claims made on

behalf of cosmetics at the present time and try to visualize how many would pass the scrutiny of the gimlet-eyed officials of the FDA with respect to effectiveness. Certainly it is clear that, particularly with drugs and new drugs, so-called "seller's puff" holds no place in the picture.

Theoretically, as a matter of law, the manufacturer may make up his own mind as to whether a product he wishes to market falls within the statutory definition of a new drug, requiring the filing of a new drug application. If qualified and authoritative experts advise him that his preparation is generally recognized as safe and effective for use under the conditions for which the product is offered, it is not a new drug and, again as a matter of strict law, there is no legal necessity for obtaining the prior clearance of the FDA. (We must not forget, of course, that if the product is in reality a cosmetic and not a drug the new drug question does not arise at all). The difficulty is that, even if the manufacturer of a drug does obtain the opinions of a number of highly reputable and qualified experts, it is quite possible that the FDA will prevail in regulatory proceedings against the product or against the manufacturer, or both, if the Agency can obtain the testimony of a couple of other qualified experts who furnish an opinion contrary to that of the manufacturer's experts.

There must always be borne in mind, the fact that, in litigation instituted by the FDA, the tendency of most courts is to accept the viewpoint of the government on the basis of the approach taken by the Supreme Court that the Federal Food, Drug and Cosmetic Act must be "liberally construed" so as to carry out its salutary purpose to protect the public. Thus, in a leading food and drug case which reached the Supreme Court many years ago, the Court stated in its opinion:

> The purposes of this legislation touch phases of the lives and health of people which, in the circumstances of present industrialism are largely beyond self protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

This is not to say that there are no instances in which a manufacturer may take advantage of his statutory right to determine whether his product, which he firmly believes to be a cosmetic, is not a drug and therefore cannot be a new drug. If, from a practical viewpoint, he has had (as, of course, he should, no matter how his product is denominated) appropriate tests conducted which reveal beyond any reasonable doubt that it will not cause injury to the public, and if all

of his promotional material (advertising as well as labeling) has been reviewed with the greatest diligence to determine that no drug-like or therapeutic claim or representation is made for the product, he has the right to make a decision that it is a cosmetic and that there is no legal necessity for filing a new drug application or seeking the opinion of the FDA. The manufacturer, of course, must have some courage, for if he is wrong, dire consequences may ensue.

What I have said does not mean that no drug-like ingredient, under any circumstance, may be included in a cosmetic formulation. There is no question in my mind but that the problem to which I have adverted is increased in magnitude by the use of a drug ingredient in a cosmetic for technological purposes. An example is the utilization of an antibiotic or other antibacterial agent solely for its preservative effect. On the assumption again, however, that no hazard is presented by the use of the antibiotic or other drug ingredient, in my opinion it is a reasonable position, and one which can be taken under the Act, that this does not automatically convert the cosmetic into a drug if no drug claims whatever, direct or indirect, are made on behalf of the drug ingredient and it is clearly employed for a non-drug use.

Conclusion

I conclude by pointing out that frequently the cosmetic manufacturer is caught between Scylla and Charybdis. On one hand he is faced with the expenditure of considerable sums of money, often the passage of inordinate periods of time, and the uncertainty as to whether his product will ever be approved by the FDA. On the other hand, if he makes the brave decision that his product is a cosmetic and not a drug or new drug, he faces a costly lawsuit, destruction of his product, and possible criminal prosecution if he has guessed wrong or been rash or badly advised. My concluding suggestion, therefore, is—be careful. **[The End]**

TIME EXTENDED FOR COMMENTS ON PRESCRIPTION DRUG ADVERTISING

The time for filing comments to the proposed amended regulations on prescription drug advertising has been extended from July 22, 1967, to September 1, 1967 (32 *Federal Register* 9320). The proposed regulations, which would require a presentation of balanced information and claims for prescription drugs, appeared in 32 *Federal Register* 7533.

Similarities of and Differences Between the Food Laws of France and the United States

By J. P. K. VAN DER STEUR

Dr. J. P. K. van der Steur Is a Member of the Food Law Advisory Committee, Nominated by the Queen (Holland) and an Advisor to the Council of Dutch Employers Organization for Food Law Problems. This Article Was Translated by Ann M. Wolf.

THE NAMES OF THE FRENCH LAW: "Law on the Repression of Frauds in the Sale of Goods and of Adulterations of Food Commodities and Farm Products" and of the American Law: "Federal Food, Drug and Cosmetic Act and General Regulations for its Enforcement" already bring out a difference in the attitude towards the problems.

Distinctions have long been made between measures designed to protect the health and regulations intended to protect consumers from deceptions. At Ankara, Turkey, a stone from the year 2,000 B.C. with the following inscription was found in a museum of Hittite Culture: "Thou shalt not poison the fat of thy neighbors. Thou shalt not cast a spell on the fat of thy neighbors." Here we have the oldest food law in which we already find the distinction between protection of the health and honest trade practices.

At the outset, the Department for the Repression of Frauds and Quality Control was meant to protect the consumer from fraudulent practices. Possibly, this difference in terminology is due to the more realistic state of mind of the French. The problems involving our health have gradually gained more and more importance, and at present, food regulations are being enacted only after an opinion has been obtained from the Superior Board of Hygiene and the Academy of Medicine. Americans have since the beginning of their legislation

made a clear distinction between protection of the health and protection from fraudulent practices.

Definition of a Food

We are going to compare the rules established in the two laws with regard to a certain number of important points. In the first place, we have to define what the countries understand by the term "food product."

The American legislation defines the term clearly and very broadly:

> Articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.

No official legal definition of the term "food" exists in France. According to Souverain, the following definition may be considered as rendering its meaning—in view of the opinions issued by a great number of physicians, hygienists and chemists:

> Foods are the products—gathered in nature and at times transformed—which man has empirically used for consumption in order to meet the energetic and plastic requirements of his body, which means his requirements in calories and materials. A food is any matter coming from nature, processed or not, which by long experience has been recognized as both good and necessary to assure by ingestion the development and sustenance of the corporeal life.
>
> This definition covers tradition, usage, long human experience, or the guarantee that the highest scientific authorities have no objection to the composition of the food.

In France, the products called "foods" are understood to comprise products which are essentially of nutritive value, as well as condiments and flavors whose nutritive value may be minimal or null. Rennet, blood, pectines, yeast, iodized salt, beverage powders, food colors, and the tap water used by the food industry are likewise considered as foods. Gums and other products intended for chewing are not classified as "foods," however, as they are in the United States, where also animal feed, which goes beyond the usual French acceptation of the term "foods," is considered "food."

In the United States, as in France, a clear distinction is made between foods and medicines: but in France, food commodities and beverages recommended because of their capacity of preventing or curing human diseases must be considered as medicines and may be sold only in pharmacies. As a result thereof, a food to which vitamins have been added in order to have it meet the requirements of a good food product, shall not have in its labeling any reference to such an addition. For instance, the addition of vitamins A and D to margarine

intended to compensate for the lack of vitamins A and D in the diet—butter meets this need by the vitamins A and D naturally present in it, which are identical with the ones added to margarine—may be mentioned only if the product with the added vitamins is sold in pharmacies. In this respect, the American legislation, which considers such a declaration as normal and useful, is much more sensible.

Definition of Food Additive

In France, no legal definition exists for food additives. From the study published by two official French representatives under the title "Control of Food Additives in France" the conclusion must be reached that all added substances, and in particular pesticide residues, must be considered additives. Only a few additives, such as colors, are being considered as foods, but otherwise, this problem has never been solved clearly. We will later refer to the reasons why.

In America, Section 201 (s) of the law gives the following definition of additives:

> The term "food additive" means any substance the intended use of which results, or may result, directly or indirectly, in its becoming a food component or otherwise affecting the characteristics of a certain food.
>
> The term "food additive" does not apply to substances generally recognized by qualified experts to be safe under the conditions of its intended use. Nor does it apply to pesticide chemicals, or to substances generally used in foods before January 1, 1958, the non-harmfulness of which has thus been proved. Any additive used under conditions contrary to the ones indicated herein shall be deemed to be unsafe and any food containing it shall be considered as adulterated within the meaning of the law.*

The American legislation actually considers food additives as foods. In his excellent article on additives, published in the May, 1966 issue of *Chemie et Industrie,* Souverain said that in France

> the thought has been to proceed from the natural composition of foods and to declare as extraneous any element present in foods in a manner which, in nature or quantity, is abnormal. To recognize a chemical substance as a *food additive* is equivalent to admitting that this substance may exist in a certain food in a generally limited proportion and that it is also a normal component of this food.
>
> The authorization to add to the same food this same chemical substance, in the same limited proportion, but as a *substance extraneous to the food,* certainly leads to achieving the aforesaid composition, but with a reservation in spirit and in language. It is a substance added to the food, an acceptable additive, but still an extraneous element. Its presence is tolerated because it is a useful servant, even though it does not belong to the "food" family. And if necessary, a

* Note of the Translator: This is a "doctored" quotation from the Federal Food, Drug and Cosmetic Act. The last sentence is based on Section *409.*

pejorative sign will be stuck to it. In short, the product named "food additive" is included in the intimacy and make-up of the food. The product named "additive to the food" is tolerated as a co-existing substance.

The results to which these two ways of thought have led are perfectly clear. In the *United States* and Great Britain, they have hundreds of food additives, and new ones are added continuously. Doors are opened frenetically to the many inventions which our steadily expanding knowledge of chemical bodies permits us to develop in the preparation of foods. In *France,* and several other European countries (Germany, Italy, Belgium), the brakes are put on almost constantly, permits are issued with moderation, and the number of additives is limited to 130 or 150.

The American interpretation takes into account the modern advances in the food industry, whose products must meet requirements which are made more stringent all the time. This applies to both preservability and usefulness for a specific purpose, and to the attraction which the product has for the housewife. Especially during the last decades, this last factor has led to the growing production of ready-to-use products, because household help is becoming scarcer and scarcer. This evolution progresses in giant steps, which means that a constantly growing number of foods is being produced industrially and, in addition, must travel over greater distances. Due to industrial processing and preservation, by sterilization or dehydration, for instance, substances which exist in the fresh food may be lost and must be replaced later. Moreover, all these modern products need more and more preservatives, antioxidants, emulsifiers and other additives required for the products of tomorrow.

The preparation of all these products demands therefore more and more that we utilize the means offered by modern science. If we restrict the use of such means by authorizing food additives parsimoniously, we give proof of a conservatism contrary to the needs of the industrial evolution.

The principle of restricting authorizations derives from

the idea that we must safeguard the notion of the pure food, as it was defended at the International Congresses on the repression of frauds at Geneva, in 1908, and at Paris, in 1909. Only under constraint and pressure does one bring oneself to authorizing the substance because, without it, the population would lack foods which are indispensable. (Souverain)

One can understand the desire as a safety measure to limit the number of authorized additives as much as possible. Only those ingredients should be permitted which after long use have proved to be harmless. But the ultra-rapid evolution of industry and sciences forces us to take new roads, of course with the necessary precautions. Without this tendency, the world of today would in many domains

offer less possibilities and be much poorer, especially if we think, for instance, of the technical advances in aeronautics (Concordé) and the ultrafast trains.

From the toxicological point of view, it may even be to advantage to spread the risk by authorizing the use of a large number of additives in small amounts. This opinion was also defended by the Joint WHO/FAO Committee on Food Additives.

Also the general principles on the use of additives (1956) established by WHO and FAO include strict rules on the safety of the additives to be authorized and on the conditions under which they might be authorized; their number is not limited, however.

Positive Lists

In France, the principle of positive lists was established already in the Decree of April 15, 1912 which provides:

> Any goods and commodities intended for human consumption are prohibited from being held with a view to selling, from being exhibited for sale, or from being sold, if chemical preservatives or colors were added to them other than those the use of which was declared lawful in decrees issued jointly by the Ministers of Public Health, Agriculture, Commerce and Industry, with the approval of the Superior Board of Public Hygiene of France and the Academy of Medicine.

This principle was generalized by the Decree of June 28, 1912, which provides:

> In all cases not specifically provided for by the regulations issued by virtue of Article 11 of the Law of August 1, 1905, no chemical products other than common salt may be added to beverages and commodities intended for human consumption.

In the United States, all food additives must be entered in positive lists in accordance with Section 409 of the law. They may be used by virtue of an order issued on a petition that is equivalent to an application for an authorization and proves their safety. Next to these additives, there are the so-called "G.R.A.S."* substances, which would probably be considered additives in other countries. Not in the United States, however, where an authorization is required only for additives the toxicological examination of which has proved their safety. The "G.R.A.S." substances, which have not undergone a toxicological examination, are considered as harmless because they were used without injurious effects over a long number of years.

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* Note of the Translator:
"*G*enerally *R*ecognized *A*s *S*afe."

One may say, therefore, that in both countries, the issuance of an authorization is indispensable for all additives used in foods, so that what prevails is the principle of prohibition i.e., only specifically authorized additives may be used.

In France, such authorizations are in some cases general in character, as for instance, in the case of flavoring agents. In a general manner, no objection exists to the use of natural or synthetic flavoring agents whose long use has made it possible to establish their safety. Certain flavors were specifically designated as tolerable: anethole, amyl acetate, benzaldehyde, vanillin, diacetyl, "cenanthol." But all of them are natural or synthetic flavoring agents identical with the natural substances. They are substances which exist in the food in minimal amounts, and the quantity added is regulated by the taste they impart.

In the United States, the amendment to the federal law of September 6, 1958 provides for the entering in positive lists of all food additives which have successfully undergone the examination ordered in Section 409, or if this is not possible, they must be "G.R.A.S." substances, the long use of which has proved that they can be "*G*enerally *R*ecognized *A*s *S*afe." These substances are likewise entered in lists, which comprise more than a thousand flavoring agents. In this respect, there exists a big difference therefore between the French and the American regulations, the latter being necessary because of the extremely strict requisites provided for by the additive amendment to the federal law. Many Americans hold the view, by the way, that the flavoring requirements go much too far, because it is not possible with the methods known at present to determine their presence in a food within a reasonable period of time. If one thinks of pure substances, there can be several hundreds of them, and it is not possible to check within a reasonable period of time if they include a substance that does not appear in the list of "G.R.A.S." substances. In any case, this is not terribly important because the amounts used are small, while natural flavoring agents, and synthetic flavors identical with natural ones, can be considered as safe after prolonged use without harmful effects. Flavors and aromatics which have thus far not been found in nature will in the long run have to undergo toxicological examinations according to certain priorities, after which time it will eventually be possible to enter them in a positive list. By that time (in 10-20 years) we may have progressed sufficiently on the chemical level to recognize all the different flavoring and aromatic substances

more easily than today. For the time being, we have to be satisfied with negative lists.

In my opinion, the French regime, which is less strict, is preferable by far to the American system, which is not fully controllable. This applies also to the French regime, but one admits it by making the requirements less stringent. What is surprising is that in France, only diacetyl was authorized as a flavoring agent in margarine, when a great many products better than diacetyl are available for the purpose. It is not quite clear what this rule has to do with public health or honest business practices.

In the United States, the listing of all food additives in a positive list, or a "G.R.A.S." list, is compulsory; but in addition, a manufacturer may apply to the Food and Drug Administration (FDA) for an authorization for any new developments and possibilities which he anticipates. If such applications comply with the rules, i.e. if they give all the necessary information on the composition, directions for use, technical or physical effects which the additive is intended to produce, the quantity required to produce such effect, the quantity determination of the substance, and the toxicological examination that establishes the safety, the FDA must authorize the use of the substance, at times on certain conditions, unless the information turns out not to be sufficient to guarantee the harmlessness of its use. Moreover, such additives are considered as foods.

Declaration of Food Additives

In France, the declaration of additives is not compulsory in most cases. The declaration is compulsory only for vinegars, certain syrups, jams, jellies and marmalades. For flavors, the labeling must include the legend "artificial flavor" when an artificial flavor was used. Jams must also bear the name of the thickener. The obligation to declare the additive is not general, therefore, but in a certain number of specific cases, additives must be declared in one way or another; for instance, citrus fruit treated with diphenyl must bear a statement to this effect. Chocolate containing vanillin must be labeled "contains vanillin"; the addition of antioxidants to fats demands that the labeling of the fat bear the name of the antioxidant added.

In the United States, one proceeded from the principle that a food product is "misbranded" (poorly labeled)* if the labeling fails to state

* Note of the Translator: The English term "misbranded" is quoted in the French text—its definition is not quite correct, however.

the names of every ingredient, except spices, flavors and colors which must be declared not individually, but as a group. This does not apply to products for which an identity standard was fixed, in whose labeling only certain of the additives named in the standard in question need be mentioned. Most standards imply the compulsory declaration of additives—but not for all of them. There does exist a growing tendency toward requiring the declaration of the ingredients included in the standards. The American regime, with declarations much more extensive than any we know in Europe, has come to make the consumer completely indifferent. So many ingredients are named of which the consumer has never heard that he no longer looks at them, but leaves the matter to the authorities whose duty it is to control food products.

This is the reason why I prefer the French system, under which a declaration is compulsory only in cases in which it is advisable for the consumer to be informed about the presence of certain additives. If food regulations function properly, such cases will be very limited in number.

In the United States, the ingredients of a food the composition of which has not been fixed in a standard, for instance, desserts, must in general be named on the package, without specifying the spices, flavors and colors, which may be designated by the generic terms "spices," etc. For standardized products, not all ingredients need to be declared. This form of declaration is in line with the rules applied to food additives in America. In France, it is generally not necessary to state the complete composition in the labeling.

New Regulations

The enactment of new rules, or the amendment of old ones, is within the province of the Department for the Repression of Frauds, which cooperates with the Ministry of Public Health; but for the application of these rules, only the Department for the Repression of Frauds is competent. The authorization of new additives depends on a favorable opinion from both the Academy of Medicine and the Superior Board of Public Hygiene of France.

In America, the FDA, which belongs to the Department of Health, Education and Welfare, is responsible for the issuance of new rules or the amendment of old ones. The FDA is the bureau whose duty it is to protect public health in so far as it depends on foods, drugs, cosmetics, etc. It has 5,000 employees. Its head office is at

Washington, and it has 18 branches distributed throughout the country. Meat and meat products are controlled by the Department of Agriculture. In this fashion, everything necessary to judge whether the use of certain raw materials or additives may be authorized has been brought under one organization.

On the one hand, such permits are based on the results of the research work done by industry in its own laboratories, or in other non-official laboratories, but on the other hand, every necessary means, such as laboratories, toxicologists, etc., is available to check the results submitted. This working method makes it possible to arrive at a decision, within the limited time fixed in the law, for example on petitions for authorizations of food additives. If the authorization is granted, it is valid throughout the entire territory of the United States.

When we compare this situation with conditions in Europe, where at this time, separate applications for authorizations to use certain food additives must be filed in every single country and where, moreover, the results of the examination made in the country of application must be submitted, we can easily recognize the enormous advantage offered by an organization such as the FDA. If we had in Europe, for a large territory including France, an organization that processes all applications from the entire territory, this would permit considerable savings and prompt processing. In addition, the availability of well-equipped laboratories would guarantee greater certainty about the safety of the authorized substances. Such an organization would provisionally operate for the E.E.C.; but later, when the E.F.T.A. will have joined it, it would operate for all of Western Europe. This is still quite far off, but if there is a will to cooperate more closely, it ought to be possible to set up such an organization within about ten years. **[The End]**

DIRECTOR OF FDA'S DIVISION OF MICROBIOLOGY NAMED

Dr. Joseph C. Olson, Jr. will become director of the Food and Drug Administration's Division of Microbiology on August 21, 1967. Dr. Olson, who has been professor of bacteriology at the University of Minnesota since 1956, is the editor of the *Journal of Milk and Food Technology.*

Forward With A Backward Look

By JAMES F. HOGE

The Following Article Was Presented at the Second General Session of the 86th Annual Meeting of The Proprietary Association on May 17, 1967. Mr. Hoge, of Rogers, Hoge & Hills, Is General Counsel of the Association.

IN 1790, IN HIS "REFLECTIONS ON THE REVOLUTION IN FRANCE," Edmund Burke wrote:

> People will not look forward to posterity who never look backward to their ancestors. (Vol. III, p. 274)

Let me say at once that neither that quotation—taken as a text—nor my title is intended to suggest that we describe where we are going in terms of where we have been, or that we see the future as in a rear view mirror. Rather, they are designed to provoke some reflections on our own revolution as it relates to the health care sector of our political economy. Of course, we must look forward and face contemporary challenge. But we will do that with better perspective if we take an occasional look backward.

Since the Kefauver hearings began in December, 1959, the drug industry has carried on in a climate of fear, apprehension and coercion. Its public image is incredibly bad. Hostility is directed principally against prescription drugs, because of their more potent therapeutic effect and price consciousness. But in the fullness of time, the turn of the proprietaries will come, and my appeal today is that you who make them be ready; that you take a backward look and see that history repeats itself—even if not in the same form and place.

Historically, the proprietaries, derisively called "patent medicines," were the objects of attack. They made up the propaganda exhibit which in the 1930's was known as "the chamber of horrors." Years before, in 1904 and 1905, they were the subject of the so-called "exposures" made by Edward W. Bok in the *Ladies Home Journal* and by Samuel Hopkins Adams in "The Great American Fraud," which appeared

in *Collier's Weekly*. These articles and Upton Sinclair's book, "The Jungle", which purported to portray conditions in packing plants in Chicago ("Packingtown"), triggered enactment of the Food and Drugs Act of 1906.

This is the sixtieth anniversary of the Food and Drug Law. The proprietary drug industry can look back sixty years with gratification and gratitude. The law as then enacted, and as revised in 1938, has been the best thing that ever happened to the industry. Standards and disciplines took form then which have now, three score years later, established the business as an industry and justified its social and economic performance.

The whole drug industry may take pride—and find incentive, too —in a backward look. Its great accomplishments, which are now so seldom remembered and so scantily appreciated, are nonetheless real. Its public image need not remain as it is. In fact, it must not, and its improvement should be a first concern.

During this sixtieth anniversary we should recall the history of the industry and should revivify its outstanding contribution to the life and health of people everywhere. The proprietary division should take pride in having come from lowly beginnings, and in now having the opportunity to make available to all people good medicines, expertly made, accurately labeled, and popularly priced. That opportunity is the challenge of its tomorrow.

Anniversary recollections should include those of the men who have headed the Food and Drug Administration (FDA) through the years. Men of loyalty and dedication, they were models of devoted public servants. Their successors' actions should stand on foundations laid by them.

Strong Foundations

We must get down to those foundations and recover the rapport between government and industry. Current antagonisms come as echoes across a third of a century. At the time of the introduction of the Tugwell Bill in June, 1933, the relations between government and the drug industry were hostile. The 1938 Act brought a reconciliation of attitude as well as of text. It distresses me to hear it said today by persons who are uninformed that the 1938 Act was forced upon the industry. It was not. I was there. I was your General Counsel, and I can testify to the fact. Specifically, this Association, from May, 1935 to June, 1938, was a diligent and faithful supporter

of the bill which became the law. Thereafter, and until 1962, there was much cooperative effort.

It was demonstrated during the past year that effort of that sort is still possible. In the last Congress, H. R. 13886, described as a "Child Safety Act", ostensibly aimed at reducing the number of tablets per package of children's aspirin. In reality, it was designed to extend vastly the discretionary delegated regulatory powers of the FDA.

After numerous hearings, the Subcommittee on Health and Welfare of the House Committee on Interstate and Foreign Commerce concluded that the limitation and packaging of tablets of children's aspirin might be better handled by conference than by legislation. A conference was accordingly held in Washington last November. Industry leaders, distinguished physicians and FDA officials agreed on the limitation of the number of tablets, on appropriate warnings and on other recommendations.

These agreements should receive your allegiance. Your spokesmen had recommended a conference to the committee and had told them that the industry would abide by its decisions. We must, therefore, keep faith with Congress. We must support the conference recommendations by fully complying with them in letter and spirit. Remember: in this we demonstrate capacity for self-regulation, and we show that future controls can minimize legislative fiat and executive edict and can accomplish desired ends by voluntary action, by conference, by education, and by cooperation.

Already, there is another such opportunity. On April 19, we appeared before the House Committee on Postal Operations for a hearing on bills to prohibit the sending to consumers of unsolicited mail samples of any article within the broad definitions of drug, device and cosmetic. We told the Committee of the experience with the aspirin bill, recommended a similar course and presented guidelines for self-regulation. We also assured the Post Office Department that industry would cooperate. The Committee now has the bills under study for some such cooperative procedure. And we must keep our promise!

The vitamin-mineral controversy now going on might have yielded to amicable settlement had it been explored with the affected industry and the scientific community. Instead, FDA, with questionable legal authority, attempted to dictate standardized formulations. Now government, industry and the taxpayer face the prospect of the

most monstrous, costly and time-consuming administrative hearing in FDA history.

Industry will have to realize that for consumer goods such as medicines "Caveat Emptor" has been replaced by "Caveat Vendor" and that the consumer has acquired a political significance far beyond his commercial status. Politicians, bureaucrats, sociologists, and economists vie with producers for his favor. The President has a Special Assistant for Consumer Affairs. He delivers an annual Consumer Message to Congress. The Commissioner of Food and Drugs has a Consultant on Consumer Relations. In the eighteen FDA districts throughout the country, there are "Consumer Specialists" to explain, says an announcement, "the life-protection mission of FDA to professional and consumer groups" and to report "consumer needs and attitudes back to FDA."

Image Building

Image building has become absorbing business at FDA. Speech writers and press agents turn out a steady stream of publicity. Coverage in the daily and weekly press is phenomenal. "FDA Papers", a four color glossy monthly publication, made its first appearance in February. It contains legal notices, news items and editorial content for advancing official views. Early this year, FDA sponsored a syndicated "Consumer Education" program in more than 400 employee newspapers in all major industries, intended to reach millions of elderly citizens and to advance the agency's views on such subjects as vitamins, cosmetics, drugs, advertising, and Rx labeling. There is an "FDA Hot Line" of recorded telephone messages, and a subscription service of interviews and reports. A one-minute spot on TV, with a statement by Dr. Goddard, was distributed to 700 stations.

This image building by the FDA is of a current governmental pattern. For persuading us that what the government does is for our welfare there are 6,858 federal employees and an annual governmental expenditure of $425,000,000. In this avalanche of publicity the government does not observe the rules of full disclosure and brief summary that it itself imposes on the manufacturers of drugs.

Excessive publicity poses important questions. At what point does it transform information into propaganda? When does it become prosecution by press release? Can regulation of the drug industry be fairly shaped, whether legislatively, administratively, or judicially, and the image of the drug industry accurately portrayed in a framework of unrelenting prejudicial publicity?

Perhaps such questions prompted Senators Dirksen and Long to include in their bill (S. 518) for revising the Administrative Procedure Act a provision that a reviewing court may set aside agency action if it finds that publicity issued by the agency discredited or disparaged a person under investigation or a party to the proceeding. A related bill by Senator Dirksen (S. 924) includes a proviso that it shall not be deemed prejudicial error if an equal opportunity has been accorded to the respondent to publicize his comments at the same time and in the same document in which the agency publicity was issued. This would be a new and welcome application of FDA's "fair balance".

Advertising Can Make and Break

Now, having had a critical look at governmental advertising, let us say something about industrial advertising, with particular regard to proprietary medicines. The 1938 law, as enacted, did not include any control over drug advertising. In the form in which it passed the Senate in May, 1935, it did. It provided a civil penalty action for violation of the false advertising provisions when the violation did not involve imminent danger to health or when it did not involve gross deception, and when it was established by opinion evidence only. False advertising was also subject to injunction.

This bit of history should be a word to the wise. It should encourage adherence to codes of good advertising practices. You have such a code. Adherence to it by each member company is of great import. If self-discipline, augmented by Federal Trade Commission (FTC) procedures, cannot compel fair advertising practices, then stronger sanctions must come. Advertising can do more than make the proprietary business; it can also break it. Unless we lay hold on our responsibility and discharge it, we will lose the confidence of the public and the respect of the government.

Contemporary attacks upon advertising are all around. They are not confined to drugs, but the unfortunate public image of the drug business has made its advertising particularly vulnerable. The Honorable Donald F. Turner, Assistant Attorney General in Charge of the Antitrust Division, has proposed that there be developed "new sources of consumer information and new methods of getting that information to consumers in convenient ways and useful forms." He has suggested, as a possible solution, the use of government funds to support "Consumer Reports", a "Medical Letter", and similar consumer information services. During the past year, Dr. Goddard ad-

dressed the Consumers Union on its Thirtieth Anniversary and stressed the need for consumer information.

In all of these respects, the drug industry is deeply involved. Regulations under the "Fair Packaging and Labeling Act" which was passed by the last Congress, are now in preparation against the effective date of July 1, 1967. We appeared before the House Commerce Committee last summer and asked that over-the-counter drugs be exempted from the law, pointing out that all drugs are already regulated as to packaging and labeling. We were unsuccessful. So, we have this further Federal control, and the contagion of it is spreading through the states.

More Regulation!

Two bills in Congress of great importance to the drug industry have been introduced by Senator Long, of Louisiana (S. 1303) and Senator Montoya, of New Mexico (S. 17). Senator Long's bill is entitled "Quality and Cost Control Standards for Drugs Act". It would amend the Social Security Act to establish quality and cost control standards and a method of payment for drugs under Public Assistance and Medicare programs. It would be Title XX. It does not directly involve proprietary medicines as usually defined. It will affect them indirectly. But the limits of its practical application cannot now be stated.

Senator Montoya's bill was co-sponsored by twenty-one other Senators. It would add "home prescriptions" to benefits under Medicare. It would permit a Government Formulary Committee to select drug products, including brand name ones, if they are necessary to assure quality. The Long bill also provides for a Formulary Committee and defines its purposes and duties. The matter of a formulary or compendium and the matter of private or government sponsorship of it are actively discussed in and out of government.

Another matter of primary concern to prescription drugs, but of general interest to the whole industry, is the investigation just now beginning in Senator Nelson's Monopoly Subcommittee of the Senate Select Committee on Small Business. Announcements, headlines, and characterizations pertaining to it are reminiscent of those at the beginning of the Kefauver hearings.

The Fountain Subcommittee on government operations will likely continue its interest in the administration of the drug law. Senator Hart's Antitrust Subcommittee of the Senate Judiciary Committee

will be active, and one of the subjects announced for possible hearings by it is advertising. Another is new drug applications.

Companion bills in the Senate and House (S. 1598 and H. R. 6165) would create a commission to recommend "feasible methods for Federal regulation of medical devices." Numerous bills at Washington and in the states, and even in the cities, propose a variety of consumer legislation and investigation, including creation of consumer departments, commissions, boards, and councils. New York City has a Council on Consumer Affairs.

Administrative activity by the FTC and the FDA continues. The concept of "uniform labeling" for all products in a given therapeutic class is emerging at FDA. And FTC frequently asserts that its actions should be "across the board" rather than on a case-by-case (or product-by-product) basis.

Conclusion

The quotation from Edmund Burke at the beginning of this article, equates motivation with movement and relates the backward look to forward focus. It is in this context that we should envision substantial change. Great issues of food and population and multiplied needs of millions of consumers may put an accent again on production, and may remind our body politic that a cardinal purpose of government once was the promotion of industry, encouragement of invention, protection of property, and stimulation of incentive.

Already there are hopeful signs that the passion for centralization has cooled somewhat. The central government, even now, is reaching out to states, cities and private institutions for help in dealing with scientific, social, and economic problems. The State of the Union Message this year projected an image of partnership between government and business.

But partnership of any kind does not succeed with one partner downgrading the other. Government, as a partner, cannot simultaneously glorify its own image and degrade industry's. The future is not to be formed in condemnation, but in dedication.

For the proprietary industry this must mean: (1) faithful adherence to quality controls in the production of its goods; (2) labeling that is accurate and adequate; (3) advertising that tells the undiluted truth; and (4) pricing that is fair. Those are high peaks, visible from all directions and attainable by an industrial posterity worthy of its ancestry. **[The End]**

The Latin-American Common Market and Food Legislation

By ENRIQUE E. BLEDEL

The Following Was Presented at the Conference of the Inter-American Bar Association, San José, Costa Rica, on April 10-15, 1967. Mr. Bledel Is Secretary of the Committee on the Food and Drug Laws of the Inter-American Bar Association.

AT THE FOURTEENTH CONFERENCE OF THE INTER-AMERICAN BAR ASSOCIATION held at San Juan, Puerto Rico in May, 1965, we spoke about the Latin-American Free Trade Association (LAFTA) and the necessity of adopting uniform food legislation.

We emphasized on that occasion that to integrate the economies of the countries which form LAFTA, something more was required than the elimination of customs barriers or the adoption of common customs tariffs. We pointed out also that integration as far as food products are concerned can be achieved only by passing uniform laws and regulations capable of promoting a more rapid and more efficient distribution of food commodities, i. e. products of vital importance to the health of the people of Latin America. In support of our thesis that uniform food legislation was necessary, we mentioned the difficulties experienced during the negotiations conducted within LAFTA when government delegates and the representatives of private industry considered the removal of the many obstacles which prevent a more rapid and more economical circulation of foods within the zone.

As a result of our exposition, we submitted a recommendation to the Board of the Inter-American Bar Association in the sense that the Latin-American Food Code be adopted as the only legal instrument to govern the

negotiations of LAFTA. Our recommendation was approved unanimously. The need for economic integration of Latin America is a matter no longer questioned by any one—unfortunately, however, it is not put into practice with the desirable ease and speed.

Six years ago, the Punta del Este Charter already pointed out in Title III, paragraph 4, the need for establishing common quality standards for foods throughout the Latin-American market, which would make it possible to expand and diversify the food trade between the countries of Latin America, with the establishment and development of basic industries, thus contributing to the economic growth of the region.

More recently, the 9th Conference of Foreign Ministers, held at Buenos Aires on the subjects to be placed on the agenda of the Presidential Conference to take place at Punta del Este from April 12th to 14th of this year, again took up the subject of economic integration of Latin America, which ought to be one of the goals in the politics of its countries, as a measure required to complement the national efforts. In order to achieve this objective, the Conference suggested, for instance:

1. The creation in the ten-year period beginning 1970 of a Latin-American Common Market, on the basis of and improving on the two integration systems already in operation: LAFTA and the Central-American Common Market;

2. The accelerated conversion of LAFTA into a Common Market. To this end, beginning 1970, a system shall be applied progressively eliminating customs duties and *other restrictions hampering reciprocal trade;*

3. The progressive *harmonization* of economic policies and instruments, and *national legal systems;*

4. The promotion of agricultural modernization programs and agrarian reforms oriented *towards an increase in Latin-American food production to a volume sufficient to provide adequately for the population* and to meet the world's ever-increasing food requirements.

The creation of a Latin-American Common Market, based on the two already existing integration systems (LAFTA and the Central-American Common Market) will, in so far as foods are concerned, require an understanding on the body of laws, the uniform adoption of which would be most practical. In fact, several of the countries which belong to

LAFTA have, in its general outlines, followed the orientation of the Latin-American Food Code, which has been the result of years of research by and exchange of scientific data between the most outstanding food scientists of the Continent. The Latin-American Food Council, which is formed by delegates from every Latin-American country, has charge of the revision and periodical up-dating of its provisions, and subsequent to the work done by it, two editions of the Code have already been published and received high praise from food scientists everywhere.

Several of the LAFTA commissions have likewise adopted the Latin-American Food Code as a model law in their negotiations on the lifting of customs duties on foods.

At the VIII Meeting of Health Ministers of Central America and Panama, held in Costa Rica in 1963, the Central-American countries asked for the cooperation of the Pan-American Health Office in preparing minimal sanitary standards for the production and industrialization of foods. To this date, the Pan-American Health Office has worked out about 400 health standards for foods which have been submitted for consideration to the Ministers of Public Health at the IX and X Meetings which the Health Ministers of the afore-mentioned countries held at Managua and Panama City in 1964 and 1965. The formation of a Latin-American Common Market will make it necessary either to consolidate the text of the Latin-American Food Code with the Food Standards which the Central-American countries may adopt on the basis of the recommendations made by the Pan-American Health Office, or to adopt either one of these legal bodies.

Another of the recommendations referred to hereinbefore concerns the elimination not only of customs barriers, but also of *all other reciprocal trade restrictions*. The disparity between present food regulations represents without doubt a restriction to reciprocal trade. The experience of LAFTA has shown how many exemptions from duty and other concessions which the member countries granted each other for foods, fail to have any practical effects due to the difference in language spoken by local trade and international commerce.

The recommendation for the gradual *harmonization* of economic policies and instruments, and of legal systems, is of fundamental importance to the effective integration of the Latin-American countries.

It is most regrettable that while government delegates to international conferences have resolved to harmonize legal systems, locally, legal texts are constantly being approved which do not follow

a uniform pattern, but, quite on the contrary, intensify the differences in the laws of the various countries. This diversity of regulatory criteria in questions of food legislation has also assumed an almost chronic character in many of the countries with a federal system of government.

In Argentina, a nation-wide tendency has for some time inclined towards the promulgation of a National Food Law. When the new Government took over, it announced, through the Department of Public Health, that it wished to adopt one single law for the entire country. The project is still under study.

In Brazil, the Government recently passed the Brazilian Food Code, through Decree-Law No. 209 of February, 1967, which, according to its Article 1, is a national law. Even though it is true that its passage signifies a reaction against the diversification of food legislation within the country, its provisions are still completely autonomous in nature and distinct from the legal bodies mentioned hereinbefore (the Latin-American Food Code and the Food Standards recommended by the Central-American countries).

The recommendation made by the Conference of Foreign Ministers wisely uses the words "to harmonize" instead of "to make uniform." One cannot expect every country to adopt eyes closed a uniform text which may not be in line with its industrial and technological developments and the characteristics of local and inter-zone trade. At the same time, a certain harmony must exist, however, if the resolutions passed at high-level international conferences are to be put into practice.

The recommendation to promote programs providing for an *increase* in food production *sufficient to provide adequately for the population* can be completely ineffective in practice, and of no practical value, if one does not eliminate legal obstacles, such as the ones originating in the diversity of the food regulations in force in each country. If one wants to assure Latin America of better health and of true social peace, it is of vital importance to find a solution to the problem of food distribution.

In order to carry out the true and effective harmonization of food regulations for the various Latin-American countries, an Inter-American Committee, to consist of government delegates and representatives of private industry, ought to be organized as soon as prac-

ticable. This Committee should serve not only as a clearing house for all information available on the subject, but should also have the power to unify criteria and accelerate the progressive harmonization of Latin-American food legislation, which would help to make economic integration a reality.

By virtue of the ideas set forth herein, we

Recommend

The creation of an Inter-American Committee consisting of government delegates and representatives of private industry, with full powers to bring about the progressive harmonization of the Latin-American food laws.

NOTE: To prevent this recommendation from remaining a mere expression of wishes which never goes beyond this conference table, Committee XIX of the Inter-American Bar Association requests that its Council consider the possibility of sending each of the Latin-American governments, through the Associations forming it, a note accompanied by copy of the above recommendation. **[The End]**

NEW GUIDELINES FOR OBTAINING INSPECTION WARRANTS ANNOUNCED

New guidelines for Food and Drug Administration inspectors to follow in obtaining warrants for inspections of factories manufacturing, processing, packing, or holding food, drugs, devices, or cosmetics have been announced by the FDA. The new guidelines comply with a recent decision by the U. S. Supreme Court in *Camara v. Municipal Court* (CCH U. S. Supreme Court Bulletin, Dkt. 92) on June 5, 1967, which ruled that a business proprietor can legally refuse to admit a government inspector unless he has a warrant. CCH Food Drug Cosmetic Law Reports ¶ 40,262.

Factory Inspection

By MORRIS AARONS

This Article Was Presented at the Meetings of the Drug and Allied Products Guild, Inc. at Chicago, Illinois, and at Los Angeles, California on March 28 and 29, 1967, respectively. Mr. Aarons Is the General Counsel and Executive Secretary of the Guild.

A PROBLEM THAT VITALLY CONCERNS ALL OF US is inspection rights of the Food and Drug Administration (FDA). Their inspectors are visiting our plants more and more frequently. Each time an inspector walks in, the owner or the person in charge of a drug firm has great trepidations because he does not know the purpose of the visit.

The visit could be because of a specific violation, or it could be a general inspection. One company, which in my opinion is well operated, reported that inspectors were visiting the plant week after week, walking around in a mysterious fashion, and picking up items. To ascertain the reason, I called the local FDA office, without giving the name of the company, and I was told that there could be many reasons for the repeated visits. There are many surveys being made at the request of the Washington office, and most of the visits of the inspectors may be solely for that purpose. I was also told that in many instances the plants are arbitrarily chosen, and the inspection may have nothing to do with any violation. The choice may be the house which is known to the district office to be carrying the kind of item or having the type of equipment under survey. This could very well be one of the better plants.

However, inspection is always worrisome, and those in charge are in a dilemma as to the action to be taken when an inspector calls at the plant. Although I do not have an absolute answer, I feel that some of the information I will give you will apprise you of some of your rights.

Prior to 1938, the FDA had no basic right to inspect the factory of any drug manufacturer. Although in practice permission was usually granted by these manufacturers, the FDA still felt the need to incorporate such a right into the Federal Food, Drug and Cosmetic Act. This was attempted in 1938 with some success when the Act was amended by Section 704. Section 704 merely provided that failure to permit entry and inspection after permission had been granted would be considered a violation of the section. This provision, of course, was not satisfactory to the FDA. Fifteen years later, in 1953, the section was amended to provide for compulsory inspection. Inspection was limited, however, to examination of pertinent equipment, finished and unfinished materials, containers and labeling. No provision was made for the inspection of records without consent.

Expanded Rights of Inspection

It was not until 1962, with the enactment of the Kefauver-Harris Amendments, that Section 704 took on its present forceful form. The 1962 Amendments expanded the FDA's rights of inspection of prescription drugs. Such inspection powers were extended to include everything bearing on the question as to whether prescription drugs which are adulterated or misbranded within the meaning of the Act have been or are being manufactured. This allows the inspection of records, files, papers, processes, controls and facilities, and includes the basic right of inspection of pertinent equipment, finished and unfinished materials, containers and labeling.

In the case of proprietary or non-prescription drugs, however, inspection is still limited solely to the basic right of inspection of these last mentioned items. No records or books of non-prescription items are subject to any inspection whatsoever and the manufacturer is free to refuse such inspection.

It should be kept in mind that although prescription drug records are the subject of inspection, this inspection is not extended to financial, sales and pricing data, or to personnel data other than the qualifications of technical and professional personnel, or to research data other than that relating to new drugs and antibiotic drugs.

The 1962 enactment of subdivision (a) (2) (B) of Section 501 of the Act, relating to the Current Good Manufacturing Practices, added a new concept of product adulteration to the law. The subdivision provided that a drug shall be deemed to be adulterated if the methods, facilities and controls used for its manufacture, processing, packaging

or holding do not conform to current good manufacturing practice to assure that such drug has the safety, identity, strength, quality and purity it is represented or purported to possess. These manufacturing controls were entirely new to the drug industry, which up to that time had only to meet sanitation requirements in the factory.

In this instance, the FDA, to implement this new subdivision of Section 501 of the Act, promulgated regulations known as Part 133, effective June 20, 1963, to provide what is considered Current Good Manufacturing Practice. The regulations specify a broad scope of procedures which must be followed by the manufacturer of drugs. Among these production requirements are criteria for buildings, equipment, personnel, components, master formula and batch production records, production and control procedures, laboratory controls, packaging and labeling, and complaint files.

There is no question but that prescription drug records kept pursuant to good manufacturing practice regulations are subject to full inspection. However, with respect to proprietary or non-prescription drugs, the whole question takes on a new outlook. The question arises whether inspection of the latter records is permitted because of the new regulations covering Current Good Manufacturing Practices.

This Section 501, although providing that a drug may be deemed adulterated if not manufactured in conformity with current good manufacturing practice, does not give the FDA the right to inspect the records of drugs which are not prescription drugs. The right to inspection is encompassed within Section 704 which I previously described. What I am saying is that the regulations promulgated by the FDA with respect to Good Manufacturing Practice do not and cannot add to or supplement the rights of the FDA concerning inspection. This right can only be authorized by Congress.

But this does not mean that the record keeping required under the Current Good Manufacturing Practice regulations concerning non-prescription drugs can be disregarded. In fact, it is most important that it be followed meticulously.

The FDA may argue, how can the good manufacturing provisions then be enforced, if no inspection of the records is permitted as to proprietaries or non-prescription drugs? How will they be able to determine whether proper records are being kept? I feel that if Congress wanted to allow for such inspection of records of such drugs, it would have so provided. It chose not to do so.

The Problem of Inspection

The problem nevertheless is a very real one. Should the factory superintendent allow an inspector to examine these records? As you know, the practice of the FDA is to inspect everything unless restrained by the person in charge of the premises. Therefore, this person is faced with the dilemma of whether or not also to allow the inspection of non-prescription drugs. This is a very perilous position to be in.

To refuse inspection may be considered as being uncooperative, and in the event of any future violation, the FDA may be uncooperative in return. It must be remembered that they have the power to demand a recall of a product and to set the extent of such a recall; they have the right to apply for an order of seizure or to apply for an injunction or recommend prosecution, as well as to give the firm involved, under certain circumstances, the opportunity to correct a situation.

Also, if the factory superintendent's judgment is erroneous and he does not allow an inspection which would have been proper, he may then have unwittingly subjected himself to criminal prosecution for violating the Act by failing to allow a valid inspection of his plant. Surely this is a terrible dilemma to find oneself in.

Although it is generally known what items are prescription and non-prescription, there may be gray areas where a dispute can arise. In a recent case, *U. S. v. Miles Laboratories, Inc.*, the question arose whether "decholin" was a prescription drug or an over-the-counter drug. A motion for summary judgment was denied. The Court held that a question of fact, which should be determined on trial, existed as to the pharmacological effect of the drug.

There are persons who feel it is imperative that the requirements for factory inspection be made more definite so that those involved in this dilemma would once and for all know exactly where they stand when inspectors knock at their doors.

The Problem of Defense Against Seizure

Beyond the problem of criminal prosecution there is the problem of seizure. Should the drug executive risk defending himself against what he feels to be an unjust seizure of his merchandise? Defending oneself is one of the basic rights possessed by all in this country. However, the drug executive finds too often that he is denied even

this basic right. He must decide in all cases the value of defending against such a seizure by weighing the benefits to be gained from such a challenge to FDA authority against the possibility of serious economic consequences which could result from any adverse publicity released by the FDA about his company.

In Court, his chances of victory are even slimmer, as the moral argument of the public health looms foremost in the mind of the Court. But even if he wins a particular suit proving his drug is not in violation of the Act, how will such publicity rest in the minds of the public when they again see this product on the market. Will they doubt the quality of the remainder of his product line?

In addition, a few moments of glory against the FDA is short lived when the same company must deal, day in and day out, with the same FDA officials with regard to decisions that affect the very life-line of their business.

For these reasons the drug industry executive finds himself well within the terms of the age-old adage, "damned if you do and damned if you don't".

Perfect Answer Not Possible

To give a perfect answer to the situation is impossible. Law is not an exact science and there always appear to be two sides to every issue.

Under the law and regulations, companies must operate under current good manufacturing practices. We assume that this is being done in all instances.

When an FDA inspector calls, ascertain whether he is there to make a general inspection or a special inspection so that at least you know the reasons for his visit. Be as cooperative as possible. If you have any serious doubts, consult your attorney. I have found the inspectors to be very understanding and cooperative. I know that it is quite disillusioning to be able to follow no other positive course of action, but this is the problem in a wholly regulated industry.

Conclusion

The Drug News Weekly said that at the Pharmaceutical Wholesalers Association meeting in Las Vegas Dr. Goddard had "ruffled more feathers than he had smoothed." He indicated his dissatisfaction with the voluntary effort of the industry to comply with Current Good Manufacturing Practice Regulations. He said there would be

more recalls and threatened more court actions. He also said that the FDA had issued instructions to field officers to recommend seizures, prosecutions and/or injunctions.

The Drug and Allied Products Guild (DAPG) has in the past vigorously protested the FDA enforcement policy of seizure, injunction, criminal prosecution, and unnecessary publicity. The DAPG will continue to do so in the future. We respect the rank and power of the FDA but we object to the use of the "Sword of Damocles." We are businessmen serving the public well. We believe in voluntary compliance through understanding, cooperation and education. We do not need constant threats and whipping.

A statement attributed to Dr. Earl L. Meyers, chief of Manufacturing Controls Branch, Division of Drugs, Bureau of Medicine, FDA, sums up the sentiment of our industry.

> The best interpretation and enforcement of law is obtained when there is clear understanding and cooperation between Food and Drug Officials and the pharmaceutical industry.

The only consolation I can offer at this moment is that I have recently had experience which makes me feel that the FDA is changing its methods of achieving greater perfection in production of drugs from giving punitive lessons to stressing cooperative educational understanding and dialogue.

If this is so, it is a step in the right direction. I predict that the FDA will find that the ends that it desires will be best achieved in this manner. **[The End]**

FDA IS FINAL JUDGE OF ADULTERATED IMPORTS

A determination by the Food and Drug Administration that salvaged coffee beans offered for import were adulterated and therefore could not be admitted was held not reviewable under the Administrative Procedure Act by the U. S. District Court in San Francisco. Section 801 of the Food, Drug and Cosmetic Act delegates authority to the FDA to determine whether a food offered for import appears adulterated, but it does not provide for judicial review. Therefore, the FDA has, by law, the discretionary power to make the final determination as to the admissibility of imported food. Also, although the owner of the food may appear before the FDA and introduce testimony, the FDA is not limited to the record of the hearing, nor is it required to make its examination a matter of record. If the examination of samples shows that the food *appears* to be adulterated, the FDA may refuse admission. The Court concluded that it does not have the authority to question whether the FDA's action was arbitrary. The FDA officers acted within the scope of their authority, and the statute is not unconstitutional. *Sugarman v. Forbragd*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,263.

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