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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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Journal

The FDA Self-Certification Program

By H. A. GOLLE

This Paper Was Presented at the 1968 Annual Meeting of Food Industry Representatives at the University of Wisconsin on April 10, 1968. Mr. Golle Is Director, Corporate Quality Assurance, General Foods Corporation.

TOO LITTLE KNOWLEDGE often leads to misunderstanding, so I would like to begin with a brief, chronological summary of events leading up to the self-certification pilot study we are currently conducting in conjunction with the Food and Drug Administration (FDA) at our plant in Dover, Delaware.

The first serious suggestion that industry be encouraged toward self-regulation was contained in a series of recommendations submitted by the Citizens Advisory Committee to the Secretary of Health, Education and Welfare in 1962. That same year, at a conference of FDA and Food & Drug Law Institute representatives, C. W. Cook, then president of General Foods, pointed out the growing need for mutual respect between FDA and the food industry. "We respect the government's function of establishing rules of fair play," he said, "and in turn we seek respect for our own sense of responsibility."

In 1964, these and other arguments for better government-industry cooperation were discussed and endorsed during a national conference on Salmonellosis conducted by Dr. James L. Goddard at the Communicable Disease Center in Atlanta. There was general agreement that traditional law enforcement no longer was the sole answer.

In the spring of 1966, Dr. Goddard discussed his concern with the National Advisory Council to FDA, a continuing group of 18 representatives of education, science, labor and industry. There was general

agreement among the group that the increased complexity of food processing and distribution, coupled with the limited resources of FDA itself, called for approaches not foreseen by the writers of the Food and Drug Act of 1938. Mr. Cook, now General Food's chairman and the food industry's only representative on the Council, volunteered to cooperate with FDA in seeking new relationships and solutions. This helped to start an informal dialogue between FDA and the industry, which became a formal dialogue beween FDA and General Foods on May 3, 1967.

On that morning, just about a year ago, two representatives from the FDA in Washington met with seven General Foods representatives in one of the conference rooms at our corporate headquarters in White Plains, N. Y. This first meeting, which was mainly a session of probing and exchanging views, lasted two days and included a general tour of our Technical Center in Tarrytown, N. Y. and of our processing plant in Dover.

Subsequent meetings were held on May 25, July 11, and August 8, and included pretty much the same personnel. Details were slowly worked out, and drafts of a self-certification agreement for the pilot study were exchanged and discussed. The final, approved document, effective September 1, 1967, was signed on August 10 by Dr. James L. Goddard for the Food and Drug Administration and by Chairman C. W. Cook for General Foods.

The Dover Agreement

This document, which we now refer to as The Dover Agreement, contains the following elements:

(1) It is concerned with product safety only, not with product elegance, that is, those factors related to consumer satisfaction, such as texture, taste and performance;

(2) It is effective for one year;

(3) It covers only two products manufactured at only one plant, Jell-O Gelatin Dessert and Jell-O Golden Egg Custard Mix. These two products were selected because microbiologically they represent both critical and non-critical food types;

(4) It spells out agreed-upon specifications, control procedures and reporting methods for the two products;

(5) It sets standards against which these controls are measured;

(6) It establishes the procedure to be followed should these standards not be met;

(7) It states the types of data to be made available to FDA, including a list of ingredients and additives in the two products,

but not formulas. At no time did FDA request formulas, because we both agreed that they were not essential to this type of program;

(8) It describes specific quality control information on the two products which General Foods will submit in monthly reports to the Baltimore office of the FDA;

(9) It states that General Foods will provide monthly summary reports on consumer complaints it receives on the two products related to health, foreign matter and weights;

(10) It states that, in return, the FDA will furnish General Foods with copies of all FDA inspections of facilities involving the two products, plus copies of any consumer complaints received by FDA concerning the two products.

Since The Dover Agreement went into effect last September 1, five meetings have been held either at FDA offices in Baltimore and Washington or at General Foods facilities in Dover and Tarrytown. Because of the need for maximum exposure, a considerable number of representatives from both sides are attending these current meetings, whose purpose is to discuss progress at Dover and to rework specifications for the two products in an attempt to eliminate excess paper work, manhours and costs. Our principal goal is to arrive at the minimum number of control points both parties feel will give assurance that the products are meeting agreed-upon standards for consumer safety. Both of us recognize that the initial plan may be too complex and may contain more controls than are actually necessary. This, of course, is common to most pilot studies.

Because we are attempting to establish both general guidelines and specific rules, FDA inspectors are spending much more time at our Dover plant than is normal—a total of over 20 man days since last September 1st. They are also picking up and sampling larger quantities of finished product from our distribution centers, a practice we have not objected to because we are just as anxious as FDA to thoroughly check the efficacy of this new system. Their detailed reports, and ours, form the basis for much of our monthly meeting discussion.

The Dover Agreement is now just past the half-way mark. I cannot actually say that it is either ahead of schedule or behind schedule. We are discovering issues neither of us anticipated. There has been a certain amount of mutual education and rethinking of the original concept. We have had to develop trust and understanding, plus problem-solving approaches acceptable to both sides. All of this takes time, because none of it comes easily to partners who classically

have had an adversary relationship. However, I would like to make some observations.

I think both of us have been a little surprised and gratified by the depth of desire on both sides to replace the traditional "watchdog" concept. Although we don't sit around and sing old college songs when we get together each month, we have reached a healthy trust level based on mutual respect for both the motives and the professional competence of the other side.

I think FDA is now pretty thoroughly convinced that General Foods and most companies in our industry always have taken seriously their responsibilities to the public, and without undue prodding. The agency has, in the past, stated that it has no choice but to protect the consumer, but that industry, in theory if not in practice, does have a choice: it can be responsible or irresponsible. Out of our continuing dialogue seems to come acceptance that where the purity of food is concerned, no one really has a choice. Public safety is a commitment which must be understood equally by both parties and practiced equally by both parties.

A Small Beginning

The pilot study at Dover, of course, is a small beginning. It contains some risk, but it holds much promise. And it is neither mysterious nor unique nor revolutionary. The airlines have maintained a remarkable record of public safety through a kind of self-certification program developed cooperatively by the industry and the Federal Aviation Administration. This program involves the daily maintenance of commercial aircraft, and a second one is now being developed for pilots. The purpose of both is to replace government regulation and surveillance with industry self-responsibility.

At Dover, we are trying to do pretty much the same thing. We are trying to reach honest agreement on what constitutes adequate, realistic protection for the consumer. We are trying to reach agreement on what controls are necessary to assure this protection. And we are trying to set up workable procedures on what steps to take when something goes wrong.

In the past, our ideas on consumer protection and FDA's ideas have not necessarily been the same. To correct this, we are now attempting to combine the best of both approaches, with the major responsibility for this protection placed not in the hands of FDA but in the hands of industry—where it belongs.

General Foods agreed to work with the FDA in this experiment because we believe that any legitimate and constructive means of

protecting the consumer has to be in the best interest of General Foods and the industry, for our entire franchise is built on public trust. And we believe there has to be a better way than stronger legislation and more public seizures, followed by the inevitable "trial by newspaper." We have yet to win one of those.

This, basically, is the option. Unless we want more regulation, we must assume more responsibility. And this requires closer cooperation with government and the establishment of the kind of meaningful dialogue that can lead to greater understanding and more respect and trust.

We have a good dialogue going at Dover. Both sides have a better understanding of each other's problems and of each other's legitimate interests and responsibilities. It is truly surprising how little we knew about each other.

Let me reassure everyone that we have not given away the keys to the vault. We have released to the FDA only as much information as we feel they legitimately need to make the current pilot study work. And this information pertains only to product safety. We have shared nothing that has anything to do with product elegance. Should the experiment prove not to be the best approach, neither General Foods nor the industry as a whole will be any more vulnerable than they were before it began.

We do not think it is going to fail. Even at this half-way point, with several problems still unsolved, we are sufficiently encouraged to be developing plans for self-certification coverage of all 23 product lines, representing some 375 product codes, at our Dover plant.

We have been asked many times by many people "What's in it for General Foods; how will self-certification benefit the industry?" Quite frankly, thus far we have been unable to answer that question to our total satisfaction. It is too soon to tell.

We feel, however, that certain incentives are going to have to be identified before the industry as a whole will voluntarily and readily participate in this type of self-certification program. As one example, it has been suggested, and FDA has expressed a willingness to consider, the establishment of some form of product seal, a kind of self-certification stamp that would be imprinted on every package of a product manufactured under a self-certification agreement. Such a plan, of course, would have to be administered with great care to assure proper use and to avoid misuse. The idea has not been refined, nor explored in depth, but FDA has shown a willingness to consider proposals along these lines. We as a company have not given too much thought yet as to marketing value of such a designation.

Self-certification also might provide a vehicle for modifying FDA's approach to the recall of products. Anything that protects us against the loss of public confidence that adverse publicity can cause has got to be a "plus."

In fact, any improvement in relationships between government and industry is a goal worth pursuing, on the possibility that it could lead to benefits for both industry and the public. As I stated earlier, the dialogue which has been carried on between General Foods and FDA over the past year has markedly increased our understanding of each other's approach to food safety, including methodology, which in turn has helped replace wasteful friction with a far more effective, efficient working relationship.

Let me stress one point in particular. Self-certification would represent a whole new way of life for our industry. It could require considerable education and re-orientation of thinking and attitudes about food safety and the responsibility for safety. It is also quite possible that quality assurance personnel would have to be trained in the science of "self-inspection."

We discovered early in our pilot study that to make the concept work you must believe in it. If you lack this conviction, all you are doing is adding one more frustration, one more area of potential conflict with the government. In fact, rather than establishing a new, meaningful dialogue, you will simply be continuing an old argument.

Ours has been a regulated industry since Massachusetts passed the first food law in 1784, and periodic legislation generally has followed changes in the industry itself, which in turn must follow the needs and desires of the consumer.

The trend to convenience foods, for example, has created a whole new set of problems for our industry. So has mass processing and mass distribution and increases in population density. Each has generated the need for greater care, and each has stimulated interest among the "watchdogs."

Do we let these new problems create a new vacuum to be filled by more government legislation and controls? Or do we assume the responsibility ourselves and minimize the need for regulation and reduce the need for inspection surveillance?

Whether you call it self-certification or self-responsibility, some form of industry-government cooperative effort seems appropriate at this time, if for no other purpose than to define what form and shape that cooperation should take. It is certainly worth exploring.

And this is precisely what we are doing through The Dover Agreement. We are exploring. **[The End]**

Prescription-Drug Advertising—Blight or Light?

By IRVING H. JUROW

Mr. Jurow, Who Is Vice President and General Counsel of the Schering Corporation, Bloomfield, New Jersey, Presented the Following on October 19, 1967, at the Pharmaceutical Advertising Club, New York, N. Y.

THIS IS A PROGRESS REPORT on the state of the advertising dialogue or, if you prefer, the advertising dilemma in the prescription-drug industry. Despite increasing frustrations, I remain an optimist. Consequently, I believe that if we persevere in the dialogue, we will eventually emerge from the darkness.

A bit of history is needed to provide a frame of reference and a proper perspective.

You need hardly be reminded of the gloomy days of the Kefauver investigation, when the advertising practices of the prescription-drug industry—as well as its agencies—were the subject of sharp and relentless criticism. Motives and integrity were impugned. The parade of examples—torn out of context, minimal in number and highly selective to prove negative preconceptions—were exaggerated into a broad and universal condemnation of the industry's entire promotional effort. The result, as you know, was the 1962 amendment which added Section 502 (n) to the Food, Drug and Cosmetic Act.

You are all familiar with the Spartan-like provisions of that section; they require the established name, the quantitative formula, and "such other information in brief summary relating to side effects, contraindications, and effectiveness" as shall be required by regulations of the Administration.

Implementing the authority granted by the statute, regulations were proposed by the Food and Drug Administration (FDA) in February of 1963, were made final in June of that year, were noticed for formal hearings on objections of the industry (which were eventually disposed of through an exchange of clarifying correspondence

between the FDA and the Pharmaceutical Manufacturers Association [PMA]), and were made effective as of January, 1964.

You are equally familiar with these earlier regulations still in effect. Section 1.105 (21 CFR § 1.105) tracks the language of the statute in requiring the inclusion of a "brief summary relating to side effects, contraindications, and effectiveness" (§ 1.105(e)) in any prescription-drug advertisement which provides information regarding indications or dosage recommendations. It calls for a "fair balance" in presenting the information on effectiveness and that on side effects and contraindications. Moreover, the latter information must appear "in reasonably close association" with the former, and have "the same relative degree of prominence" (§ 1.105(i)).

"Brief summary," "fair balance," "relative degree of prominence," "reasonably close association"—though these are "words of ordinary English," they nevertheless reflect imprecise, and therefore flexible, criteria, since they define by objective not measurable by a slide rule. It was not surprising, therefore, to find that they produced subjective reactions; that reasonable men honestly differed as to the application of these criteria to any particular piece of promotional material.

The optimism that was reflected in the exchange of interpretive correspondence in the Fall of 1963 was, however, short-lived. The change in administration which followed shortly thereafter was not only a change in personalities; it was a change in philosophy, in attitudes, in concepts. The words of the regulation, accordingly, took on a new and decidedly different meaning.

As a consequence, the next two and a half years witnessed a continuous exchange of mutual, sharp criticism. Broad attacks by the Administration on the advertising and promotional practices of the industry, public criticism of the journal ads of companies of high repute, government press releases in significant number, a spate of seizures, a crop of criminal indictments, produced agonizing cries from industry for rationality and for definition of the ground rules.

The dimensions of the confrontation may be measured by the fact that the FDA considered it of sufficient importance to justify the publication of a 67-page document entitled "Compendium of Medical Advertising."

The government's response to industry's complaints has come in the proposed revised regulations published in the *Federal Register* in May of this year (32 F. R. 7533, May 23, 1967). Objections have been filed and we now await the final regulation.

That the Administration considers that it is indeed responding to the industry's "request" for "clarification" of the earlier regulation is evident from the very first preamble to the new proposals. If, however, the Administration believes that what follows in the dozen columns of single-spaced, 8-point type set out in the *Federal Register* is "clarification," the volume of critical comment that has been filed should disabuse it of that belief. If the industry did, indeed, ask for clarity, it may very well reap a whirlwind of confusion and a paralysis of its promotional effort.

Difference in Attitudes

Basic to the government-industry confrontation is the obvious difference in attitudes toward the role of advertising. The FDA has failed either to recognize or to fully accept the function of advertising in promoting prescription drugs: it is promotion addressed not only to an exceptionally learned audience, but one which has readily available the totality of the approved information in the product brochure authorized by the FDA.

The proposed regulation appears to be based on the premise that each and every piece of advertising must be prepared and disseminated on the assumption that it is the *only* information which the prescribing physician has, or will use, to evaluate the drug. Advertising, however, does not function in a vacuum, nor does it function as a reference monograph. It is but one component of an informational mix which includes many other and more detailed data from many sources. Apart from the fact that the FDA's assumption depreciates the usefulness and function of all the "labeling" available, and particularly the authoritative package insert, it does a grave injustice to the medical profession. I refuse to believe that the medical profession is so irresponsible as to fail to investigate thoroughly the full recital of facts set out in the product information insert, or that physicians fail to obtain "full disclosure" from the other competent and authoritative sources available to them for that purpose, and that they prescribe, instead, relying upon the abbreviated information in promotional advertising.

It may well be that in the critical prescription-drug industry advertising should be created with greater care, with sharper attention to nuances and semantics, and with the same superior quality-control that characterizes our products, as distinguished, perhaps, from ordinary consumer products and consumer advertising. But that is a question of degree. It does not mean, nor does it follow, that the

mission of prescription-drug advertising is any more expansive than advertising in general.

Its role, its purpose, is to stimulate interest in the advertised product and to call attention to it. Once that interest has been aroused and information as to the product's availability broadcast, other means to convey in detail the nature and the uses of the product are not only available, but should be used. These include medical texts, medical meetings, journal articles, detailmen, and above all, the "full disclosure" of labeling.

It is true that the current regulation, as well as the new proposal, provide for some relief in "reminder" advertising. As defined by the proposed regulation, however, this exemption is all but meaningless. Reminder advertising, in the pristine form acceptable to the Administration, may do for the physician who is fully informed and needs only the stimulus of the name of the product. To qualify for the exemption, reads the proposal, the advertisement must "not recommend or suggest by printing or graphics any indication for use, drug dosage, or claim for safety, effectiveness, or other quality of the drug." To the physician who has yet to become acquainted with the product, or to have his memory joggled, so bare an advertisement conveys nothing. Unless, for example, the allergist is at least told or reminded that the product is an antihistamine available for his allergic patients, why should his interest be aroused? Nevertheless, under the proposal, even so casual an observation is an "indication" requiring expansive information in the advertisement.

In enacting Section 502(n), Congress recognized what is common knowledge: that advertising is informative, not instructive; that it is an attention-getting mechanism, not a statement of directions for use. Since it authorized regulations requiring a true statement of information relating to side effects, contraindications, and effectiveness, but only "in brief summary," it did not authorize regulations requiring advertisements to assume the role of a textbook on pharmacology. Moreover, it is obvious that Congress did not intend, and could not have meant, that "full disclosure," which is required in "labeling," should also be the test, albeit to a limited extent, for prescription-drug advertising.

Recall what was said by Congressman Harris, co-sponsor of the 1962 legislation:

> Are we going to say that we expect the physicians . . . to practice medicine by an advertisement contained in a magazine somewhere? If that is what you are going to say, let me show you how difficult it would be to include everything about a drug in an advertisement in some medical journal somewhere.

When you try to say that everything with respect to side effects, contraindications, and effectiveness (is) to be put into an advertisement somewhere, I can say to you it is not possible to do it.

I think it is almost an insult to the medical profession to give the impression that they practice medicine from advertisements in medical journals.[1]

If advertising is to reflect something different from "labeling," if "brief summary" is to have *any* meaning short of "full disclosure," if promotion is to serve its proper function, then obviously promotional material must contain a subjective selection and omission from the text of the approved labeling, and it is in this area of subjective selection and omission that our differences arise.

None of us wishes to compromise with the basic requirement that prescription-drug advertising and promotion be honest, truthful and accurate. On the other hand, I see no inconsistency in achieving these objectives while still permitting advertising to perform its real and primary function.

Less a Science than an Art

Advertising is less a science than an art. By its nature it is open to a variety of interpretations. No standard can assure that every individual will view or interpret an advertisement in the same way. I commend to you Justice Holmes' observation:

A word is not a crystal, transparent and unchanged, it is the skin of a living thought and may vary greatly in color and content according to the circumstances and the time in which it is used.[2]

As I have indicated, advertising and promotional material are informative, but not in the same sense as "labeling." To achieve its purpose, advertising must do less. As a practical matter, if the drug product is to be used by the patient, it must be prescribed. To get it prescribed, it must be brought to the attention of the physician to encourage him to investigate its uses and, if persuaded, to employ it. To require that advertising give him the complete "full disclosure" story is asking too much of it.

In its comments on the proposed regulations, the Pharmaceutical Advertising Club said:

Good medical advertising sells drugs through the factual, accurate and timely presentation of information. Its function is to promote the use of a drug within its therapeutic potential for the alleviation of illness and to do so in accord with good medical and good business practices. In this sense it is informative as well as factual and accurate. Medical advertising cannot carry the responsibility of being, by itself, the educational vehicle whereby physicians learn of drugs. It must recognize, must be based upon, and should (in a measure) contribute to the background of physicians which they acquired at medical schools and in hospitals, through research in laboratories and clinics, and the dissemination of

[1] 108 Cong. Rec. 19924, Sept. 27, 1962.

[2] Holmes, J., *Towne v. Eisner*, 245 U. S. 418, 425 (1918).

research and clinical findings by scientific articles in recognized medical periodicals, by the dissemination of these in reprint and abstract form, by scientific papers delivered at meetings and symposia, by scientific exhibits, and medical reporting.

Just as we demand that our prescription products be safe and effective, so should their advertising be effective, as well as safe. Safety is achieved by honest, fair, nondeceptive, and nonmisleading advertising; effectiveness is achieved by utilizing the techniques implicit in good advertising to obtain reader attention, reader interest, reader investigation, and reader *use* of the advertised products. Unless advertising is thus effective, as well as safe, it represents a waste of money.

Indeed, there is danger in allowing or encouraging physicians to believe that they may rely upon advertisements for full information, and if this be the result of the proposed regulation, we shall be doing the public and the medical profession a grave injustice.

In short, the proposed regulation of the FDA ignores the traditional and well-understood role of advertising as distinguished from a compendium, or even package-insert labeling.

What is therefore needed, it seems to me, is a rational appraisal of the role and function of prescription-drug advertising, a more valid distinction between it and "labeling," and the adoption of guidelines specifically to be applied to each. But in so doing we must avoid overburdening the function of prescription-drug advertising, and in turn depreciating the function of labeling. ". . . we should not," said Congressman Harris, "by legislation, require (advertising) to be something which it cannot be."[3]

I can hardly do justice to the wealth of critical comment that has been filed with the FDA responsive to the published proposals. I should say to you, however, that a serious question has been raised as to whether or not the proposed regulation is arbitrary, an unlawful extension of the statutory authority, and so vague as to pose serious constitutional questions since criminal sanctions may be the result of violations. This question has presented us with a serious challenge to defend advertising.

Definition of Advertising

One of the targets of this challenge is the proposal of the FDA to define advertisements (§ 1.105(1)(1)), an effort which would appear to be responsive to the suggestion that there be a rational reappraisal of the roles and functions of, and the distinction between, prescription-drug advertising and labeling.

[3] 108 Cong. Rec. 19927, Sept. 27, 1962.

As is pointed out, however, in the detailed comments filed by the PMA, the proposed definition subjects to the regulation not only those advertisements published in "journals, magazines, . . . periodicals, and newspapers," but also those "broadcast through media such as radio, television, and telephone communications systems."

That the inclusion of the latter media is beyond the authority granted by the Congress follows clearly from a reading of Section 502(n) and its legislative history; the statute applies, by its express terms, only to "printed matter." The further provisions of that Section fortify this conclusion. They provide, you will recall, that the established name must be "printed" in half-size type, and also that the Section is not applicable to any "printed matter" determined to be labeling.

These clear references to "printed matter" preclude, in our view, embracing in the FDA regulation prescription-drug advertisements disseminated through the media of radio, television, or telephone. Lest this rouse public concern that such advertising is, therefore, unregulated, it should be noted that the very Section relegates it to the jurisdiction of the Federal Trade Commission under the Federal Trade Commission Act.

Moreover, the FDA may also be able to regulate such advertisements indirectly by requiring the labeling, over which, of course, it has exclusive jurdisdiction, to contain adequate directions for use and appropriate information with respect to *all advertised uses.*

Expansive Definition of Labeling

A second target of the challenge is the expansive definition of labeling set out in the proposed regulation (§ 1.105(1)(2)). In addition to the well-known items, such as "brochures, booklets, mailing . . . [and] detailing pieces, file cards, bulletins," and the like, the FDA proposes now to include "sound recordings" and "similar pieces of . . . audio . . . matter."

But the exercise of the authority under Section 502(n) to determine what is labeling, as distinct from advertising, must be consistent with the statutory definition of labeling (§ 201(m)). Section 201(m) of the Food, Drug and Cosmetic Act defines "labeling" to mean "all labels and other written, printed, or graphic matter" on the product or its containers or wrappers, or "accompanying" it. The term "label" is defined (§ 201(k)) to mean a "display of written, printed, or graphic matter" on the immediate container of the product.

Both "label" and "labeling," you will observe, are defined in terms of "written, printed, or graphic matter." Since they hardly can

be characterized as "written, printed, or graphic matter," are "sound recordings" and "similar . . . audio . . . matter" properly included in the definition and subject to FDA regulation?

A second and perhaps more critical question is posed by the fact that the proposed regulation treats this long list of items, including such things as "calendars, price lists, catalogs, house organs, letters, . . . films, film strips, lantern slides, . . . [and] exhibits," as labeling if they "concern" a drug. Note that the regulation says "concern," not "accompany." I have already referred to the statutory definition of "labeling" and pointed out that it requires the matter to "accompany" the product to be deemed "labeling." Notwithstanding court decisions that have expanded the meaning of "accompanying" (*Kordel v. U. S.*,[4] *U. S. v. Urbeteit*,[5] *cf., Alberty Food Products v. U. S.*[6]), the requirement has not yet been completely eliminated. It is true that the decisions tend to adopt a functional rather than a physical test to determine whether the test of "accompanying" is satisfied. But it certainly cannot be said that in *all* instances the items referred to are "labeling," since many do not ordinarily accompany the drug, even in the functional sense. In our view, therefore, the definition of "labeling" in the proposed regulation reaches too far and, in all likelihood, is an unauthorized exercise of the delegated authority.

Basic Requirement

The proposed regulation starts out with a basic requirement that prescription-drug advertisements include a "true statement of information in brief summary relating to side effects, contraindications, and effectiveness." An objective is thus established consistent with the specific intent of the Congressional enactment. Proceeding from that point, the proposed regulation defines four components, any one of which causes the advertisement to fail to satisfy that requirement and objective, and the regulation then proceeds to set forth some 34 examples of practices which would cause the advertisement to violate the law.

The 4 and 34 "blackbirds" so elaborated (§ 1.105(e)(4)(e)(5)) are oriented toward the entire advertisement, not merely toward the "brief summary." Moreover, they constitute *per se* violations, a regulatory procedure which can hardly be reconciled with the vagaries of advertising, where, since circumstances and context differ so widely, a rule of reason should be applied.

[4] 335 U. S. 345 (1948).
[5] 335 U. S. 355 (1948).
[6] 185 F. 2d 321 (CA9, 1950).

For example, the concept of "fair balance" reflected in the proposed regulation reminds me of the flight of a shuttlecock in badminton—one for you and one for me. Whether, as is argued in one of the comments filed, the requirement that there be "fair balance" throughout the "advertisement as a whole" (§ 1.105(e)(2)(i)) goes beyond the statutory authority of Section 502(n), which merely calls for the inclusion in advertisements of a "brief summary," need not detain us, for that is a complex legal question. However, in the context of good advertising and promotion, and without in any way minimizing the need to be honest, truthful, and accurate, is it necessary or rational, or realistic in practice, to demand the "simultaneous" or "immediate conjunction" interweaving of adverse information with claims for safety or effectiveness (§ 1.105(e)(5)(ii), (xxvii), (xxviii))?

Similarly, is there any basis, either in the statutory authority, or by setting up the standards of linear measurements of advertisements as is proposed, to require, in addition to the "brief summary" contemplated by the Congress, a "brief discussion summary" (§ 1.105(e)(5)(xxix)(b)) comparable with the "full disclosure" required in "labeling" (§ 1.106(b)(3))?

To require not merely the inclusion of adequate and accurate information, but to regulate format, style, design, and even the very position, of the text, is surely at least arbitrary; moreover, since violation invites criminal indictment, it may come dangerously close to "cruel and unusual punishment."

I must say in all candor that no copywriter can feel safe in preparing prescription-drug advertising under these minutiae of regulatory detail without having at his side, weighing every word, graph, illustration, and perhaps punctuation mark, a lawyer expert in regulatory practice, and even he, I dare say, could not assure you that the end result would be snow-white innocence.

If the objective were to eliminate or sharply decrease prescription-drug advertising, one could hardly imagine a more effective set of regulations to that end. Surely the progress of medicine will not be advanced by the government's requiring copy to be revised solely to change the manufacturer's reference to "cuts [and] scrapes" to read "abrasions [and] lacerations," nor by debate as to whether a product should be labeled an "antihistaminic/antipyretic" or an "antipyretic/antihistaminic."

Shortly before the publication of the proposed regulations, an official of the FDA, J. Hauser, stated the objectives of the Administration in these words:

It is the goal of FDA to assure that the labeling and advertising of prescription drugs convey to physicians truthfully, adequately, and effectively the best available drug-use information. This goal simply means: The labeling and advertising of a prescription drug shall faithfully furnish the doctor the information each of us wants him to have in mind when he is about to use a drug on us or on those we love![7]

Can anyone quarrel with such an objective? Is there any doubt that pharmaceutical manufacturers and their advertising agencies fully support this goal, conscientiously strive to achieve it?

Our frustrations and conflicts derive from what I suggest may be an apothegmatic answer to these questions: The purpose is appealing, but the procedure is appalling!

The halcyon days when agencies, like lawyers, could feel secure because it was the client who went to jail are gone, and responsibility is the agency's as much as the client's. Accordingly, you have the right to demand that the regulations by which you must abide be clear and unambiguous, that they be rational and practical, and that they allow for the creativity and innovation characteristic of modern advertising, which admittedly has played a major role in the development of the economy of this country.

Although it may be of little consolation, you are aware that the criticism of prescription-drug advertising is but a part of the attack on advertising in general.

This is not the time and place to review the current governmental scrutiny of all advertising and its relation to our free market economy. You should, however, be aware of the publicly expressed attitude of the chief of the Antitrust Division, as well as the in-depth defense of advertising by Professor Backman in his book, "Advertising and Competition."

You therefore have the problem that all advertising faces, though yours may be an additional one because you serve a special audience, and sell special products, products that people need but do not want because they believe, quite understandably, that they have a constitutional right to be healthy and to be free from disease.

You need, therefore, to be ready to defend, not prescription-drug advertising alone, but all advertising, just as all advertising needs to defend prescription-drug advertising. An industry that is marked by annual expenditures in excess of $15 billion and that is singularly honored by a special column in the prestigious *New York Times* surely

[7] Food & Drug Law Institute Seminar, April 14, 1967, Northwestern University School of Law.

is important enough to merit a "handle-with-care" label. More than a quarter of a century ago, Franklin D. Roosevelt said of advertising:

> The general raising of the standards of modern civilization among all groups of people during the past half century would have been impossible without the spreading of the knowledge of higher standards by means of advertising.[8]

Advertising, as a means of communication and information, has always been creative and imaginative. But these proposed regulations will surely hobble and lessen the effectiveness of prescription-drug advertising if they destroy those characteristics. If these regulations stereotype advertising, and dictate form, placement, design, and content, quite apart from, and above, truthfulness and accuracy, and straitjacket the creativity that has characterized the history of advertising in this country, we may end up with superefficient—but surely colorless and ineffectual—ads.

Whether advertising is a "blight" on the economy or whether, as we contend, it does indeed shed "light," will be reflected in what you and the advertising community do to revive its image. **[The End]**

INTENSIFIED DRUG PLANT INSPECTION

Dr. James L. Goddard, Commissioner of the Food and Drug Administration, disclosed that the FDA plans to conduct an intensified drug plant inspection program in the coming fiscal year. The Commissioner, who was speaking to the annual Rutgers Pharmaceutical Conference in New Brunswick, N. J., stated that the intensified inspections will be made of certain firms—about 250 of them—which have a significant history of violations resulting in disciplinary actions. The FDA's aim in doing so, he stated, was not to shut down companies, but to "provide a greater measure of public confidence in drugs."

Dr. Goddard said that under intensified inspection, federal inspectors will be present in a drug plant from the start to the end of many runs so that they can make valid criticisms and suggestions. If the FDA then finds that the firm does not, or cannot, measure up to good manufacturing practices standards, steps to keep its products off the market will be taken.

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[8] Address before Annual Convention of the Advertising Federation of America, June, 1931.

Food and Drug Legislation in Central America and Panama

By ANDRZEJ E. OLSZYNA-MARZYS

Mr. Olszyna-Marzys Is a Member of the Institute of Nutrition of Central America and Panama.

IN THE JULY, 1967 ISSUE OF THIS JOURNAL,* an article entitled "The Latin American Common Market and Food Legislation," by Mr. Enrique E. Bledel, contained a brief analysis of food legislation in Latin America as a whole. Mr. Bledel describes efforts to harmonize the legal provisions in force in each country, in connection with the existence of the Latin American Free Trade Association (LAFTA) and the proposed creation, by 1970, of a Latin American Common Market.

While the latter large-scale conception is still not much more than a dream, and will require a lot of intelligent effort and good will, encouragement that it may one day become a reality can be taken from the success of a smaller organism of the same nature and in the same area which can be considered as a pilot project and indeed a nucleus of the proposed larger enterprise—the Central American Common Market.

The Central American Isthmus between the frontiers of Mexico and Colombia, with a total area of only 188,500 square miles and a population estimated at 15,000,000 (although with the rate of population growth highest of all the regions of the world), is divided into six small but fully independent republics (plus the territory of British Honduras or Belize destined for independence shortly but claimed by Guatemala). Since the attainment of independence from Spain in the first half of the nineteenth century efforts to integrate the area politically have not been very successful. In spite of its relatively small size and common history, the area represents extreme geographical, ethnical and cultural diversity and its component parts have been,

* 22 FOOD DRUG COSMETIC LAW JOURNAL 402.

and still are in many cases, entities isolated by geographical obstacles and lack of adequate communications. The independent development of the six republics since independence has also resulted in great diversification of their detailed legislation, including food and drug legislation, in spite of the common original basis.

The organization of the Central American Common Market, with Panama not yet a full member but taking active part as associate member in many of the activities of its institutions, has been an effort to tackle the problem from another end first—economic instead of political.

The success story of this venture, although inevitably slowed down in the most recent few years, is today common knowledge. One of the most notable phenomena has been the remarkable growth of trade—more than tenfold between 1954 and 1963—among the countries of the Common Market: from $8,300,000 in 1954, it reached $36,000,000 within a year of its establishment (1961), $50,000,000 in 1962 and more than $80,000,000 in 1963.

A further result has been rapid industrial development, increase in both exports and imports to and from the countries outside the zone, and increase in the consumption of consumer products.

In both production and exports, agricultural products occupy the first place in all the countries concerned. Exports from the countries of the Isthmus to those outside the zone have consisted principally of food products, with an average of 70% of the total, while in the intrazonal trade the percentage was 29%, being exceeded only by manufactured goods. The food industry, in relation to others, holds the major part of industrial capital, occupies most labor, adds a major part to the national product and constitutes, as just shown, the second largest item in inter-Central American trade. In 1962 food and beverage manufacturing plants constituted 32.1% of all industrial enterprises, employed 36.9% of total labor, had 47.9% of total fixed capital and produced 50.3% of total gross value of industrial production.

From the quoted figures it can easily be seen that the food industry is the most important activity of all the industrial branches of the Central American Isthmus. Its growth has also been progressing at a fast pace. Between 1955 and 1965, the gross value of the average annual growth of the food industry was 7.6%.

Need for Adequate Legislation

Such fast expansion obviously requires adequate legislation, regulation and normalization to protect both the pocket and the health of the consumer, and to maintain the high quality of exports in order to gain and maintain world markets in the face of fierce competition. This competition has been rapidly increasing, coming not only from industrialized countries but also from the newly emerging countries of Africa and Asia, especially in view of the fact that virtually all the main products exported by Central America—coffee, cotton, bananas, sugar—are also produced in those two continents.

Furthermore, in order to promote intrazonal trade within the Isthmus instead of hampering it, uniformity of legislation and reciprocal acceptance of control measures are essential.

Meanwhile, food legislation in the six countries of the area at the beginning of the Common Market era was quite inadequate to cope with the rapid industrial and commercial expansion, being based mainly on the general Sanitary Codes and isolated regulations (for example, those referring to milk, meat, salt and flour). According to findings of consultants commissioned by the Pan American Health Organization between 1963-1965, "the Codes were either antiquated and disjointed, or were invalidated by other regulations, or their enforcement was impossible due to lack of trained personnel." Only Costa Rica possessed a few food standards, although in all the countries moves were under way to bring the codes and regulations based on them up to date. Progress, however, has been slow.

Two distinct patterns of food and drug control can be distinguished among the countries of the Isthmus; the first is what one could call the "Anglo-Saxon" pattern, where the enforcement of food and drug legislation, including inspection of food and drug factories and collection of samples of both, is vested in the same organization, and analysis is made of both foods and drugs in the same official laboratories. This is the situation that exists in the United States of America, Canada and the United Kingdom. Two of the countries of the Isthmus have this system: Nicaragua and Panama.

The other pattern, which we might call the "European-Continental" type, is where the control of foods and that of drugs are completely separated, being covered by distinct legislation and enforced by different organizations, the drug control being usually entrusted to the pharmaceutical profession, which guards this prerogative rather jealously. This type of situation exists in Costa Rica, El

Salvador, Guatemala and Honduras. It may be added, however, that even in one of the two countries with the joint "Anglo-Saxon" type of food and drug control, namely Panama, marketing of drugs must now be approved by the National College of Pharmacists before being submitted for registration (period: 5 years) to the FDA, which in this case stands for "Farmacias, Drogas y Alimentos"—a department of the Ministry of Labor, Social Security and Public Health, which nevertheless corresponds roughly in its functions to the Food and Drug Administration of the United States.

It may be mentioned that in addition to registration of pharmaceutical products, the Latin American practice of requiring registration of processed foodstuffs has been heretofore in operation in Costa Rica (period: 6 months for imported products, 1 year for national ones, no fee), Guatemala (period: indefinite, nominal fee for analysis previous to registration) and Panama (period: 10 years, fees for registration itself and for an analysis previous to it).

Decrees Issued

Food and drug control was put on a rational basis in Panama through three decrees issued on the basis of the Sanitary Code of November 10, 1947: No. 256 of June 13, 1962 which in 260 articles presents very complete food regulations; No. 93 of February 16, 1962, which regulates drugs in a similar way; and No. 6 of April 18, 1963, which created the above mentioned FDA. Moreover, toward the end of 1961 the University of Panama inaugurated LEA, or Laboratorios Especializados de Analisis, a very amply equipped and staffed laboratory for food and drug analysis, which has been legally designated as the official food and drug laboratory for the Republic, and has been acting as a drug reference laboratory for the whole of the Isthmus and as a center of training for its food and drug laboratory staffs.

The other country with the combined food and drug control, Nicaragua, is not so favored, since its food legislation is based on a very antiquated and deficient Sanitary Code, although the decree No. 568 of March 11, 1961, has rationalized the registration and control of pharmaceuticals. Nevertheless, the FDA, with a name identical with that of the corresponding organization in Panama, is well organized and staffed and carries out vigorous inspection work.

Laboratory facilities are represented by a section of the Public Health Laboratory, as is the case in all the other countries as far as food analysis is concerned, except for Panama and El Salvador.

Of the four countries with separated food control and drug control, three carry out food inspection through sections of the Veterinary Public Health Departments of the Ministries of Health. In one (El Salvador), inspection is the responsibility of the Environmental Health Division, which also has its own food control laboratory.

In Costa Rica, the old Sanitary Code was revised on November 2, 1949, by Decree No. 809/49, with article 249 dealing with food control, but a completely new Code has been under consideration by the National Assembly for some time. There exists a series of regulations on specific foods and a dozen or so food standards elaborated by the Standards, Industrial and Technical Assistance Committee of the Ministry of Agriculture and Industries, established by Law No. 1698 of November 26, 1953 and Executive Decree No. 6 of September 21, 1951, the only national standards committee in Central America.

The College of Pharmacists, in charge of drug control (with analyses carried out at the Faculty of Pharmacy of the University of Costa Rica), lost the registration and control of generic and official drugs to the Registration Council of the Ministry of Health in April, 1966.

In El Salvador, food legislation has been based so far on Article 90 of the almost 40-year-old Sanitary Code of October 13, 1930 (although a new one has been under consideration) and on decrees regulating the production of milk and meat and their products. Registration of processed foodstuffs is now being introduced. Drug control and registration (renewable annually) is ultimately in the hands of the Superior Council of Public Health but is effected in practice by a pharmacist responsible to it; there is virtually no inspection or analytical control.

In Guatemala, drug registration is for an indefinite period and is effected by the Inspectorate General of Pharmacies and Narcotic Drugs of the Ministry of Health, without any previous or subsequent analytical control, although such is effected for the registration of processed foodstuffs in a relatively well-equipped laboratory.

The legislative basis is the Sanitary Code of April 30, 1937, in which articles 144 and 158 deal with registration and inspection of foodstuffs respectively, and article 40 provides for drug control. There exists also a number of decrees dealing with specific subjects such as milk production, salt iodization, flour enrichment, etc.

Finally, although in Honduras food legislation, inspection and analytical control were perhaps weakest of all the Isthmus, recently vigorous steps have been taken to remedy the situation. This country was the first one to actually promulgate a new Sanitary Code (of November 14, 1966), and on the basis of its Title V, articles 83-103, to present for ministerial approval early this year a very comprehensive food control ordinance.

At the same time, steps were taken to strengthen food inspection and laboratory services. Drug registration (for 3 years) is effected by the College of Chemistry and Pharmacy established by a decree of August 29, 1963, with the local University contracted to effect analyses.

In view of this diversity of legislative and organizational positions and general inadequacy of control services, it is not surprising that the regional organs should feel urgent need for uniform legal provisions, and for reorganization and strengthening of enforcement services, also on a uniform basis.

Requests for Assistance

The six Ministers of Health, gathered at their eighth regular annual meeting in San José, Costa Rica, in 1963, officially requested the assistance of the Pan American Sanitary Bureau, the Regional Office of the World Health Organization (PASB/WHO), in the field of food control.

One of the first needs, it was felt, was the introduction of a set of common minimum sanitary food standards. Although one of the regional institutions, the Central American Research Institute for Industry (ICAITI), had been entrusted with establishing standards for all industrial products, those are the voluntary trading standards specifying quality grades and only a few of those issued to date referred to food products. PASB/WHO commissioned the Adolfo Lutz Institute of Sao Paulo, Brazil for the work of preparing obligatory sanitary standards and at the same time initiating and financing regular annual Seminars of Food and Drug Control for Central America and Panama, grouping representatives of the control services of the six countries. In 1963-1965 a set of about 380 food standards, including analytical methods, lists of permitted additives, etc., was elaborated, revised at the Seminars, presented to the Ministers and recommended by them for inclusion in the legislations of the six countries.

In this work, in addition to national laws and standards of many countries, the provisions of Latin American Food Code and the work of the Joint Food and Agriculture Organization/World Health Organization Codex Alimentarius were taken into account. However, it was felt that the former offered only very general principles while the work of the latter proceeded rather slowly and neither included standards for specifically local Central American products nor took account of local conditions. Therefore, this more detailed set specifically adapted to local needs was felt necessary.

PASB/WHO has also been helping in the strengthening and reorganizing of food inspection and laboratory services in the area. Detailed proposals for their uniform organization and for uniform regulations were made by PASB/WHO consultants especially at the last Food and Drug Seminar (in 1967). These referred particularly to such things as a common system of registration of processed foodstuffs with validity of five years and identical scale of fees, pesticide residue limit lists, etc. They were accepted by the group and recommended by them to the Council of Ministers of Health, who in turn adopted them and recommended their inclusion in national legislations.

By the resolution of the Ministers, the Institute of Nutrition of Central America and Panama (INCAP), situated in Guatemala City and administered by PASB/WHO, was asked to organize a new Division of Food Control and Analysis which would act as a Regional Food Reference Laboratory.

Under PASB/WHO auspices, a large-scale project is now being elaborated by INCAP for an integrated food control organization, which could include all the national food inspection and laboratory services, as well as the new Division of INCAP, the LEA and the standardization section of ICAITI, and it is hoped to obtain the assistance of the Special Fund of the United Nations Development Program for the project.

Summary

If all these labors succeed, it will be yet another important step in the integration activities of the area, the ultimate goal of which might be a political union, the aspiration of the best sons of Central America for some hundred and fifty years. **[The End]**

A Reasoned Approach to Regulation Based on Toxicologic Considerations

By JOHN P. FRAWLEY

The Following Article Was Presented at the National Conference on Indirect Food Additives Held in Washington, D. C., Tuesday, February 13, 1968. Dr. Frawley Is Chief Toxicologist for Hercules, Incorporated, Wilmington, Delaware.

ALMOST 2400 YEARS AGO, one of the greatest philosophers of our culture, Plato, advised the rulers of ancient Greece: "Nothing is more unworthy of a wise man, or ought to trouble him more, than to have allowed more time for trifling and useless things, than they deserved."

I do not pretend to be a wise man, but I am troubled and the majority of the toxicology profession is troubled because we spend so much time on trifling and useless things. In no other area of environmental health have we invested so much time and effort in unprofitable research, as we have on indirect food additives.

I think the very fact that this National Conference on Indirect Food Additives is being held constitutes a recognition by government that our priorities should be re-evaluated. I also think that this Conference has been called because the Food and Drug Administration (FDA) sincerely wishes our opinions and advice on how we can protect public health in a more efficient manner than with our current regulatory procedures on indirect additives. If my assumption is correct, we have the unprecedented opportunity to offer our suggestions and the responsibility to propose specific constructive mechanisms to improve our system.

I think it is imperative in any discussion of environmental health to put the specific subject in perspective. Our environment is composed completely of chemicals, most of which are of natural origin

and only a small percentage of man's invention. Despite the well-established fact that the most highly toxic chemicals are of natural origin, toxicologists spend most of their time evaluating the *potential hazard* from man-made environmental chemicals. There are many historic and religious reasons for our preoccupation with man's contribution to the environment rather than nature's, but that is a subject for another discussion.

If we limit our considerations to man-made or synthetic products, toxicologists are faced with the staggering task of evaluating the safety of air pollutants, pesticides, drugs, direct food additives, water pollutants, cosmetic chemicals, synthetic fibers, rocket exhausts, industrial chemicals in our plants, indirect food additives, and so on. There is a severely limited supply of toxicologists and other experts qualified to work in this field and from a national and international point of view, any concentration of emphasis on one problem dilutes the effort on the other problems. The same can be said of our financial resources. Even in this country there are limited funds available for environmental health research, and any concentration of effort on one problem restricts the funds available for other problems.

Commissioner Goddard and his staff at the FDA recognize these limitations on manpower and money and constantly must re-evaluate priorities so that major health hazards receive the Administration's major effort. Ten years ago when the 1958 Amendment was passed, the degree of health hazard from food packaging was unknown. Consequently, a relatively high priority was assigned to this source of environmental exposure. In these intervening years we have learned that the potential health hazard is slight but we have not yet figured out a mechanism for reducing our effort and at the same time provide protection against some future development which might pose a threat to health.

As many of you know, about two years ago I became disturbed about the continuing investment of government and industry resources in the investigation of safety of trivial uses of food packaging components. I realized that I personally had spent over a million dollars of my Corporation's money investigating the safety of food packaging materials, and from society's point of view it was all wasted, because all were proven to be safe. The benefit to the consumer was zero. The loss to society was a million dollars. I also realized that this situation had been repeated in laboratories throughout the country with the net result that essentially all of the practices of the food packaging industry prior to the 1958 Amendment had been confirmed as safe

and inscribed into a set of regulations too complex for anyone to understand. I felt that it was time to re-evaluate our priorities.

In trying to determine what decisions had been responsible for this waste of effort, it was apparent that the toxicology and legal professions had failed mutually to cope with the problem of insignificance or "de minimis" in a reasonable and intelligent manner. The two professions had not reached a mutual understanding of the concept of toxicological insignificance and as a result its validity was denied. This is the heart of the problem which not only plagues us in the field of indirect additives, but in all areas of environmental health. If we are to avoid continued waste, we must recognize the validity of this concept and with the help of our lawyers find some mechanism to put it to work for us.

Let me briefly describe a typical situation which I conservatively estimate has occurred a thousand times in the field of food packaging. A manufacturer is trying to evaluate the safety of a food packaging component. His bright young chemist with a new and expensive analytical instrument discovers that 10 parts per billion of a chemical migrates from the container to food. The lawyer says that because it can migrate to food, it is a food additive and must be established as safe. The toxicologist says that he cannot conclude that it is safe until toxicologic studies are conducted. This is the ever famous trichotomy which we have all experienced.

Alternatives in Establishing Insignificance

Now there are three obvious ways to break this vicious circle. First of all the chemist can say that it isn't there. He can use a less sensitive analytical method and report a negative finding and then the lawyer and toxicologist aren't worried because as far as they know it isn't there. Secondly, if the chemist doesn't want to say it is not there, the lawyer can say "de minimis non curat lex"—the law does not concern itself with trifles—and conclude that the Food and Drug Law was not intended to concern itself with these minuscule contaminants. Thirdly, the toxicologist can say it is safe on the basis of insignificance.

In my opinion, the responsibility for finding an intelligent solution to this problem rests with the lawyers and toxicologists, and not with the chemists. Chemistry is an exact science, unlike toxicology, and it is scientifically dishonest to ask a chemist to prove the absence of something by using the least sensitive analytical technique which he thinks will satisfy the toxicologist. I wonder how often this is done, because 10 parts per billion of a chemical is considered legally

a food additive if detected, but if "not detected" at a sensitivity of 10 or even 100 parts per billion it is not considered a food additive.

A number of my scientific colleagues attempt to put the blame on our lawyers. I disagree. I think toxicologists have the initial responsibility to decide what is insignificant, and secondarily lawyers have the responsibility for using the law and regulations as a mechanism for putting sound scientific principles into operation. The regulations should not be a straight jacket for the scientist, but a vital, living instrument used in a flexible manner to provide the greatest protection of health in the most efficient manner. As new scientific knowledge is evolved, the procedural and interpretive regulations should be modified to reflect this knowledge rather than remain outmoded, permanent obstacles to a rational scientific conclusion. I submit that lawyers and toxicologists can work together to solve this problem. Our objective is the same—maximum protection of public health.

Guidelines for Establishing Insignificance

Because I considered it to be the responsibility of the toxicologist to break this vicious circle, I tried to develop some workable guidelines which could be used by our profession in deciding insignificance. I first had to ask myself: can any safe level of a compound be established without toxicologic data? My first answer was no, probably because I have heard this said so many times that I accepted it as fact. I then realized the illogical conclusions which follow such a position. If we consider one molecule of a chemical potentially toxic until we have proven otherwise by toxicity studies, we cannot allow synthesis of any new compounds because the chemist will be exposed to at least one molecule. Conversely we cannot conduct a toxicologic study until the chemist makes the compound. We do in practice and in fact accept one molecule of an unknown chemical as safe because we have never discovered a chemical which would be toxic at this level and because we realize that the alternative would be unacceptable to society.

Next, I asked myself: can we consider a dietary concentration of one part per billion of a compound to be safe without toxicity data? My first reaction again was to answer no, but then I realized that we do in fact make this assumption everyday of our lives. Every time a chemist synthesizes a new compound, his exposure exceeds this level. Every time a chemical is handled in development to determine its physical properties and usefulness, the exposure exceeds this level. If we did not allow this to take place without toxicologic

studies, the toxicologist himself and his technicians would be exposed to more than one part per billion in the process of investigating its toxicit . Again we routinely accept one part per billion as toxicologi ally insignificant because experience has confirmed that it is valid.

The third question I asked myself was: can we consider one part per million of a compound to be safe without toxicity data? Here my answer was emphatically no, because experience has taught us that a few compounds cause minimal toxic effects at this level and a few chemical warfare agents cause severe toxic effects at this level.

This exercise in self-questioning led me to the following conclusions which help us understand toxicological insignificance: Some human exposure must take place before animal toxicologic studies can be conducted. Every human exposure from the moment a chemist synthesizes the first molecule constitutes a toxicologic experiment in itself, which tells us something about the compound. The degree of human exposure which can be allowed without formal animal toxicologic studies is based entirely on experience. The only alternative is to prohibit the synthesis of any new chemical.

Review of Chronic Toxicity Studies

Because experience is the only basis for deciding what can be considered toxicologically insignificant for migrants from food packaging, I decided to examine our experience as thoroughly as possible. Since most of our decisions on safety of consumer products are based on long-term toxicity studies, I decided to search the biological literature for every chronic toxicity study which has ever been conducted and to tabulate the safe or "no toxic effect" level for each compound. I restricted my tabulation to chronic studies because most shorter term studies are not published and "no toxic effect" levels from shorter studies are not considered conclusive by some toxicologists. After my initial effort on this project became known, other toxicologists in industry, government and universities helped by furnishing me obscure references and unpublished reports.

I can make no claim that I have found every two-year chronic toxicity study which has been conducted. I can only claim that I have tabulated the "no toxic effect" levels from every chronic study which I could find, without any selection or rejection. In total, I have been able to locate two-year chronic toxicity studies on 245 different substances, and although this may seem like a modest number, it represents between 15 and 20 million dollars in toxicological research. I estimate that I now have collected over 90% of all such studies

which have ever been conducted. I have presented these tabulations at two scientific symposia on food packaging and the complete details and documentation have been published in the journal of Food and Cosmetics Toxicology.[1]

In brief, this review of our toxicological experience, based on the most stringent test available, revealed a marked difference between the toxicity of the class of chemicals developed as pesticides and heavy metals (which indeed were also used as pesticides at one time) and the class I refer to as "all others." This is an important observation, even though it is almost self-evident, because it points out that what is toxicologically insignificant for one class of compounds need not be toxicologically insignificant for another. For the "all other" category, which excludes pesticides and heavy metals, every compound was without toxic effect in experimental animals when fed for a lifetime at a dietary concentration of 40 parts per million. Most compounds were safe at considerably above 100 parts per million.

The Margin of Safety

Therefore, if we apply the conventional 100-fold margin of safety advocated by the FDA to protect against unpredictable human sensitivity and make the standard adjustment for the greater intake per unit of body weight of experimental animals, every compound which has been studied is safe for man at a total dietary concentration of 1 part per million. The analysis reveals that if we had permitted all of these compounds in man's diet at a level of 1 part per million without conducting any toxicological studies, public health would have been protected just as well at a saving of from 10 to 20 million dollars in toxicological expenses alone.

Although this experience indicates that we could accept 1 part per million as a level of toxicological insignificance, I recognize that my tabulation is only 90% complete. I also recognize that chronic toxicity studies, although most suitable for calculation of safe levels, may not give a completely unbiased cross-section of chemicals. It is for this reason I have proposed that we protect ourselves by another factor of ten and adopt 0.1 parts per million as a level of toxicological insignificance for all materials other than pesticides and heavy metals.

This is what experience has taught us. But at this extremely low level of insignificance, we need not rely solely on toxicological experience for protection. As I mentioned earlier, during the time that a new compound is synthesized, its usefulness explored, a pilot plant

[1] "Scientific Evidence and Common Sense as a Basis for Food Packaging Regulations," 5 *Foods and Cosmetics Toxicology Journal* 293, 1967.

operated, while it is being manufactured, packaged and used in the food packaging industry, some degree of human exposure has taken place and something has been learned about its toxicity. Responsible manufacturers conduct toxicologic studies routinely to protect their workmen, but even if no formal toxicologic studies have been conducted, a compound which could be toxic to man at 0.1 parts per million would have revealed its extremely high toxicity in these exposures and it would have been rejected as incompatible for the food packaging industry. It might be suitable as a chemical warfare agent, or perhaps a pesticide, but it could not be sold or used in the food packaging industry because this industry does not practice a level of industrial hygiene compatible with handling this type of compound. If employes in this industry wore fresh-air masks and full skin coverings, we could not make this statement. Again what is toxicologically insignificant for one industry or use of a compound, is not necessarily toxicologically insignificant for another.

This proposal that we consider 0.1 parts per million as a toxicologically insignificant level for food packaging components was made originally at an American Chemical Society symposium almost 18 months ago. Since then I have not learned of a single commercial chemical which might be used in food packaging which would be an exception. As many of you know, this proposal has received overwhelming support from my profession. Twenty-four other toxicologists from universities and industries have supported this proposal in writing to the FDA. Almost as many others have privately supported it. I believe the body of scientific fact and opinion justifies immediate adoption of this concept by FDA.

Relating Insignificant Level with Specific Uses

Now for a few minutes, let us address ourselves to the problem of relating this insignificant level in the diet with specific uses of chemicals in food packaging. Quite obviously, if it can be demonstrated that a given use of a chemical in food packaging will contribute no more than 0.1 parts per million to the diet of man, it should be considered to be safe without animal toxicologic studies.

Major components of a food container certainly possess the capability of migrating to food at a level in excess of 0.1 parts per million and the degree of migration and dietary contribution must be determined. However, there are some levels of use which do not possess this capability. Our initial problem is to establish a dividing line below which significant migration to food cannot occur. We have attempted to develop such a dividing line.

Undoubtedly, this dividing line is different for each type of substrate, as plastic, paper, cellophane, etc. However, for the purpose of establishing a level which would allow insignificant migration to food and which would be applicable to all substrates and additives, we selected for study the substrate which is well known to be the most permeable and susceptible to extraction; namely paper, and we selected an additive which is very readily extracted from this substrate: namely, rosin size. This combination of substrate and additive represents the most extreme example of migration, and values determined from rosin sized paper should represent a maximum for any component of any packaging media. Indeed, such data would be excessive for most uses of packaging components.

In our initial efforts to study the migration of rosin size from paper, we used typical simulated solvents: various aqueous solutions, hexane, vegetable oil, etc. This type of extraction test was wasted effort because, in water and oil, the extraction was a direct function of time and temperature and did not plateau until essentially 100% of the rosin size was extracted and the integrity of the paper sheet was destroyed. Although these extraction studies clearly demonstrated that rosin sized paper would be an appropriate choice for developing maximum migration data, they contributed nothing to the evaluation of safety of rosin size.

As a consequence of this failure of the simulated solvents test to help define the amount actually migrating to food, we prepared radioactive samples of rosin size, incorporated them into typical commercial paper and paperboard, packaged a wide variety of food in contact with these paper samples at typical package ratios, stored them at typical storage temperatures for typical storage times and determined the rosin size content of each food by counting the radioactivity. In effect, we conducted an experimental market basket survey to determine the maximum amount which could be contributed to the total diet.

The study was far more extensive than I have time to describe today, because we used several types of paper (greaseproof, waxed, unwaxed, etc.), containing three different levels of rosin size, 24 different types of food (water, ice-cream, oysters, apricots, green beans, dry breakfast food, sugar, doughnuts, ground beef, butter, bacon, sausage, to name just a few) and analyzed each sample at several different storage intervals and temperatures. For our purpose of developing data on a dividing line, we selected only the uncoated and unwaxed paper and only the maximum migration levels obtained for the 18 commodi-

ties packaged in these uncoated papers under typical commercial storage conditions. Admittedly this gives unrealistically high values for rosin size which are not typical of industry practice, but for our objective, the worst case had to be selected.

I shall not present these data in detail, since they also have been discussed thoroughly at two scientific symposia and published in scientific journals.[2, 3] However, these studies represent the most extensive effort that has been made to correlate levels of use of a packaging material with dietary contributions and represent a valid experimental basis for calculating maximum total diet contributions. Briefly, they demonstrate that at a level of use of 1.0% the maximum dietary contribution will be 0.5 parts per million and at a level of use of 0.2% an insignificant amount or no more than 0.1 parts per million will be contributed to the diet.

This conclusion by necessity must apply to the food contact surface. If a compound is used in a surface treatment, as in a coating or in an antistatic treatment, this surface treatment must be considered the food contact surface and to limit migration to the insignificant level of 0.1 parts per million, the compound cannot be present at a level in excess of 0.2% of that surface treatment.

Undoubtedly this dividing line is unduly restrictive for most uses of packaging components. Many materials used at higher levels in less permeable substrates than paper, will contribute less than 0.1 parts per million. For example, a more limited study of actual migration to food has been conducted with a radioactive plasticizer used at 28% in a polyvinyl chloride film.[4] A similar analysis of these data suggest that a 0.6% level of an additive in plastics will contribute no more than 0.1 parts per million to the diet. The data are insufficient for me to propose the adoption of this dividing line for plastics, but they clearly confirm that paper and rosin size are a suitable choice as the extreme example of migration to food. Perhaps some carefully directed research will permit establishing other dividing lines in the future.

This conclusion that 0.2% of a component in a food container was safe also received overwhelming support from other experts. Because of this support I submitted a formal proposal to the FDA to incorporate this concept in Regulation 121.2500, which would ex-

[2] See footnote 1.

[3] "Migration of Rosin Components from Sized Paper to Exposed Foods," 48 *TAPPI* 8, 1965.

[4] "Toxicity of 2-Ethylhexyl Diphenyl Phosphate," 8 *Archives of Industrial Hygiene and Occupational Medicine* 283, 1953.

empt from petitioning "substances used at a level of no more than 0.2% by weight of the container or no more than 0.2% by weight of the coating or other surface treatment, provided these substances are not heavy metals. . . . . or pesticides. . . ."

By proposing the inclusion of this statement in 121.2500 (d), the other good manufacturing practice provisions of that regulation are automatically applicable to these substances: namely, that the substance is used "in an amount not more than reasonably required to accomplish the intended physical or technical effect in the food contact article" and that it is of "purity suitable for its intended use." Also, it is understood without stating it, that any such substance must comply with the Delaney Clause of the 1958 Amendment which prohibits use of known carcinogens.

As I mentioned earlier, two dozen experts have advised the FDA of their endorsement and have encouraged the Administration to adopt this proposal. Several lawyers have advised me that this support from the scientific community of and by itself confirms that these uses are generally recognized as safe or "gras" and that no action on the part of the FDA is necessary. I will not enter into a legal debate on this premise, but I think the evidence is clear that uses at or below this level of 0.2% offer no significant hazard to health, that they are unworthy of the scientific and administrative effort of industry and government required to study, petition and regulate these materials.

The Validity of the Reasonable Assumption

So far I have tried to present a scientific basis for selecting some level of use of a component in a food container which can be assumed to be safe without migration data and without toxicologic data. One additional guideline is needed to help prevent the continued waste of effort and that is a level of migration for components used at levels above 0.2% which also can be considered safe without toxicologic studies. We frequently refer to this type of component as "non-migratory." It is a logical extension of my previous proposal that we adopt the same level of 0.1 parts per million as a level of no significant migration. If a use of a major component can be confirmed by suitable analytical studies to contribute no more than 0.1 parts per million to the diet, it also should be considered safe. An important point in the interpretation of the data from such studies, is that reasonable assumptions of food contact and consumption should be allowed rather than the arbitrary assumptions that all food is packaged in

small one ounce containers, and that the entire diet is composed of the type of food to which greatest migration occurs, even if it is vinegar. No-effect levels and acceptable daily intakes by definition are intake levels and they must be compared with intake levels in man—not with theoretical maxima which have no relationship to intake or total diet levels.

Conclusion

To conclude this discussion very briefly, I and many of my colleagues in the toxicology profession propose that we accept 0.1 parts per million in the total diet of man as a toxicologically insignificant level of a food packaging component—with the exception of pesticides and heavy metals. We have also proposed that a level of 0.2% by weight of such a component in a finished container or food contact surface be recognized as safe in the regulations because it cannot contribute more than 0.1 parts per million to the diet. Thirdly, we propose that major components which can be shown by suitable migration studies to contribute no more than 0.1 parts per million to the diet should be considered nonmigratory. The other uses, and only these other uses which migrate at a significant level are worthy of toxicologic study and government regulation.

Thus we propose three categories of food packaging components: 1) those used at 0.2% or less which *cannot* "reasonably be expected" to become components of food, and these should be exempt, 2) those used above 0.2% which *may* "reasonably be expected" to become a component of food, "*but in fact do not*," and these should be considered nonmigratory, and 3) those used above 0.2% which *are* indeed food additives and should be subject to appropriate examination for safety and regulation under the law.

Only by accepting some level of insignificance and recognizing the relative risk to public health from different uses can we avoid wasting our resources on predictably unprofitable research. It is our moral responsibility as scientists and it is the vested responsibility of government to invest our time and money in research which is likely to provide the greatest protection to health. Ten years ago, we lacked the scientific basis to evaluate the relative hazard associated with indirect additives. Today, after investing tens of millions of dollars and man hours, we know that the relative risk is small. I propose that we benefit from this knowledge and restore an equitable balance to our environmental health program. I have tried to suggest a few ways to achieve this objective. **[The End]**

Report of the Fifth Session of the Joint FAO/WHO Codex Alimentarius Commission

By FRANKLIN M. DEPEW

Mr. Depew Is President of The Food and Drug Law Institute, Inc.

THE FIFTH SESSION of the Food and Agriculture Organization (FAO)/World Health Organization (WHO) Codex Alimentarius Commission was held at FAO Headquarters, Rome, Italy, February 20 to March 1, 1968. The session was attended by about 150 registrants made up of delegates and observers from some 42 countries and 20 international organizations, as well as other interested observers. The total Commission membership as of the time of the meeting was 52 countries — 23 in the European region, 2 in North America, 7 in Latin America, 8 in Africa, 2 in the South West Pacific and 10 in Asia.

The session was opened in behalf of the Directors-General of FAO and WHO with a welcoming speech by Dr. A. H. Boerma, Director-General of FAO. Dr. Boerma specially welcomed the new members of the Commission and emphasized the importance of the work of the Commission in helping remove non-economic obstacles to international trade. He paid tribute to Professor Dr. M. J. L. Dols of the Netherlands, the retiring Chairman of the Commission.

Composition of Fifth Session

The United States Delegation consisted of 12 representatives including Mr. George R. Grange, Deputy Administrator, Consumer Marketing Service, U. S. Department of Agriculture (USDA), its Chairman. Mr. Grange was assisted by Mr. F. Robert Anderson of the Consumer Marketing Service, USDA, and by the following industry representatives:

Irving A. Hoff, U. S. Cane Sugar Refiners Association; Leonard K. Lobred, National Canners Association; Jan J. Mertens, National Canners Association; Michael F. Markel, Esq., Washington Attorney; Donald M. Mounce, Campbell Soup Company; Robert G. Ruark, Corn Products Company; Howard C. Spenser, Dow Chemical Co.; R. Malcolm Stephens, Institute of Shortening and Edible Oils; J. Bryan Stine, Kraft Foods Division of National Dairy Products Corporation; Robert J. Olson, General Foods Corporation.

During the session the Commission elected Mr. J. H. V. Davies of the United Kingdom as Chairman to serve from the end of the Fifth Session until the end of the Sixth Session. The Commission also elected Professor Dr. Otto Hogl of Switzerland, Mr. E. Mortensen of Denmark and Mr. I. H. Smith of Australia as Vice-Chairmen for the same term. The Commission also elected the following member countries of the Commission to represent the indicated geographical locations on the Executive Committee:

For Africa — Ghana;
For Asia — Japan;
For Europe — Poland;
For Latin America — Argentina;
For North America — U.S.A.;
For South West Pacific — New Zealand.

The following briefly reports the progress made and the other principal actions taken by the Fifth Session of the Commission.

Important Progress

Among the promising steps taken by the Commission was the approval at step 9 of the Codex procedure of the standards for canned tomatoes, canned green beans, canned peaches, canned applesauce, canned sweet corn, glucose syrup, dried glucose syrup, dextrose monohydrate, dextrose anhydrose and lactose.

Approval at step 9 leaves only the acceptance of the standards by governments before the Commission can take the final step of publishing them as Codex standards. The approval of the first standard at step 9 was greeted by spontaneous applause.

Also approved at step 9 were Codes of Practice for general principles of food hygiene and hygienic practice for canned fruit and vegetable products. The Commission agreed that these Codes were advisory only but that parts of these Codes, especially those dealing with end product specifications, would be included in Codex standards

and could then become mandatory. The Commission further concluded that the statutes of the Commission concerning the protection of health of consumers gave it sufficient authority to continue its work on Codes of Hygienic Practice, but sought the legal advice of counsel of FAO and WHO as to its authority relative to codes of practice generally.

The canned fruit and vegetable standards include a provision that the listings of food additives are subject to endorsement by the Codex Committee on Food Additives. The Chairman of the Committee, Mr. George R. Grange of the United States, explained that a number of countries felt there was no technological necessity for certain of these additives but that the Committee agreed in general that if an additive were used in one or more countries which are significant producers of the product, the additive should appear in the standard in order that it can be reviewed by the Codex Committee on Food Additives and the Joint FAO/WHO Expert Committee on Food Additives. Mr. Grange had said earlier, in connection with a discussion of flour treatment agents which were objected to by many European countries, that if food additives are recognized as safe by the technical experts there must be some give-and-take if we are to have standards. Those opposing their use must consider the differing food habits in the various countries which make it essential for some countries to use these flour treatment agents. His forceful support of this point of view on both of these occasions contributed greatly to the final acceptance of these fruit and vegetable standards at step 9. The Commission agreed that if a food additive is only "temporarily" endorsed by the Food Additive Committee at the time a commodity standard which provides for its use is sent to governments for consideration, it would bear footnotes stating "temporary pending toxicological evaluation" or "temporary pending assessment of the total food load."

Those who believe in the Codex program expect that the United States should have little difficulty in accepting the standards approved by the Commission at step 9. FDA has already established standards for canned tomatoes, canned green and wax beans, canned sweet corn and canned peaches and has proposed standards for applesauce and for canned grapefruit. The canned fruit and vegetable standards approved by the Commission are very close to the FDA standards. The food hygiene codes of practice, which are guidelines rather than standards, resemble closely the "good manufacturing practice" regulations proposed by the Food and Drug Administration (FDA). No standards have been proposed for sugars but it is anticipated that

FDA will propose such standards in the near future. If the Codex program is to be successful, the United States must establish such standards, for it cannot accept the Codex standards and enforce them here unless there are comparable U.S. standards. If the United States shows a willingness to give on some points now, there should be a better chance of other countries giving on provisions of later standards. Such action on our part will exemplify the policy of give-and-take so eloquently expressed by Mr. Grange at the meeting and reported earlier.

The audience granted by His Holiness, Pope Paul VI, should operate as an incentive to all delegations to work more effectively toward the goal of harmonization. The Pope commended and encouraged the work of the Commission and invoked on its deliberations richest divine graces and favors.

General Principles

At the third session of the Commission the Committee on General Principles, chaired by France, had recommended three ways of accepting a Codex standard: (1) Full Acceptance; (2) Acceptance with a Declaration of More Stringent or Supplementary Requirements; and (3) Target Acceptance. These were approved by the Commission at that time and have remained basically unchanged since. At the Fifth Session this Committee submitted the wording of these three ways of acceptance for Commission review and suggested that it would be possible to better achieve the objective of acceptance if a fourth method of acceptance, namely, "Partial Acceptance," were made available to cover cases where the circumstances peculiar to a country might require it to permit less stringent provisions for some parts of a Codex standard. The Commission adopted the texts as recommended for the first three ways of acceptance, although a number of objections were made to Acceptance with a Declaration of More Stringent or Supplementary Requirements. It was pointed out that if a standard fulfilled the purposes of the Codex Alimentarius then there should be no need for more stringent requirements and that recognition of this formula constitutes approval of differing standards since each country can establish stricter criteria than those appearing in the standards. The three Vice Chairmen of the Commission redrafted the text of the fourth method of acceptance to make it clear that the "less stringent requirements concerned only minor matters" and to provide that these "minor" deviations would have to be accepted by the Commission. The Commission decided not to adopt the draft at this time but to ask governments for com-

ment, and it requested the Committee on General Principles to reconsider the proposal after the government comments are received.

Food Labeling

The Codex Committee on Food Labeling, chaired by Canada, reported on the proposed General Standard for the Labeling of Prepackaged Food. The Commission considered the standard and decided to advance it to step 6. During the discussion questions were raised about the listing of ingredients in general, and, in particular, the listing of standardized products for which it was suggested an exception should be permitted. The view was expressed by some that the declaration of ingredients without proportion is more likely to confuse the housewife than inform her. Some countries queried the provisions of the standard requiring declaration of net contents on the label. It was also suggested that it would be helpful if labels should, in addition to the units of measurement used in the producing country, also show the measurement according to the metric system. Some delegates expressed the view that the label should be dated. The Committee report indicated there might be some foods which should bear an expiration date, but stressed the need for sound scientific justification for such a procedure. The Committee said the individual commodity committees should consider whether it is necessary that the labels of any commodity being reviewed by them for standardization be dated. The Committee has not finally settled the question of specifying type sizes. The Commission is referring these matters to governments for comments and they will be discussed again by the Committee at its next meeting, after receipt of these comments. The FAO Secretariat reported that it is preparing a paper dealing with national legislation in regard to the exemption of foods from ingredient listing and that this paper should be completed in time to be considered by the Committee at its next meeting.

Standard for Margarine

The Commission spent an entire day discussing the provisional margarine standard. The standard was examined section by section. In view of the divergence of opinion regarding a number of basic provisions of the standard, it was decided to keep the standard at step 8, to instruct the Secretariat to redraft the standard in the Codex format, to send the redrafted text to governments for comments, and to submit the text and comments to the Executive Committee which would decide whether to refer the standard back to the Codex Committee on Fats and Oils or to recommend that the Commission re-

examine it at step 8 at its next session. Disagreement on the standard involved use of milk products in margarine, moisture content, both maximum and minimum fat content provisions, use of vitamins and food additives, and the coloring and labeling provisions. Mr. Grange, for the United States, pointed out that a maximum moisture content of 16% could operate to discriminate against unsalted margarine. He also pointed out that the United States would have to change its standard to allow marine oil if the standard were passed to step 9, but felt that this could be done.

Standard for Honey

Also considered at step 8 was the provisional standard for honey drafted by the Coordinating Committee for Europe. At the fourth session of the Commission this Committee had been asked to study the proposal that this standard be worldwide rather than regional. In reporting on the standard the Committee recommended that it be approved as a regional standard. The Committee further reported that it had taken into account views of interested non-European countries with the result that differences between European and non-European countries had been considerably narrowed. There was extensive debate as to whether the text of the standard should be considered first or the question of whether the standard should be regional or worldwide. France argued that procedurally the European region alone had the right to vote on whether or not the standard should be regional. This view did not prevail but the Commission members voted 16 to 13, with four abstentions, that the standard be considered as a regional one. The regional standard in its present form would set high levels for enzyme activity, preventing heat treatment of honey. In behalf of the United States, Mr. Grange reported that 55% of random samples tested did not conform to the proposed standard. He commended the efforts to secure a standard acceptable to all and said the United States would continue to work with the Committee to that end. The standard was kept at step 8, to be sent to governments for comments and to be re-examined at the next Commission meeting, having in the meantime been referred to the Coordinating Committee for Europe for review, if the Executive Committee decided this was advisable. Proponents of making it a regional standard said it could later be amended to serve as a worldwide standard.

Regional standards such as this would be barred under a proposal made by Canada which would limit regional standards to "food produced exclusively and consumed mainly within the geographic region."

The Canadian delegate said regional standards for commodities which move in world trade might operate to restrain trade. The Canadian proposal will be sent to governments for comments and considered at the next session.

The Commission requested the Executive Committee to examine the desirability of introducing a greater degree of flexibility in the procedure for elaboration of standards, in particular, with a view to enabling a standard under consideration at step 8 as a regional standard to be considered as a worldwide standard at the same step.

Packaging Materials

At the request of the Fourth Session of the Commission, the Secretariat prepared a paper on packaging materials, outlining the subject. The Commission noted that the Council of Europe had established a Working Party to deal with the control of packaging materials. The Commission agreed with the conclusions of the Codex Committee on Food Additives that before packaging materials were considered, a large amount of preliminary work would have to be done on compiling information for consideration by a Joint FAO/WHO Expert Committee.

The Commission then examined the priority which should be given to the consideration of the subject. Mr. Grange pointed out that there were many other additive problems which are more urgent and recommended deferring for at least a year. In view of the fact that the existing Expert Committees and the Codex Committees still had a number of classes of food additives, contaminants and pesticide residues with high priority to consider, the Commission decided that no action should be taken at this time, and that the outcome of the investigations of the Working Party of the Council of Europe should be awaited before further action was taken on this subject. The Commission was of the opinion that meanwhile the Secretariat of FAO and WHO should collect data on the migration of packaging material components into food and on their toxicity.

Food Standards Work in Africa, Asia and Latin America

At the Fourth Session of the Commission the Secretariat was requested to prepare a survey of the needs of African countries in respect of food legislation and standards. The Commission was informed that the Secretariat had obtained some information from the various African countries and that a certain amount of data had been received through the offices of the FAO Regional and Country

Representatives stationed in Africa. The Commission was also informed that the document which the Secretariat had prepared had been found useful by other services in FAO whose function was to advise developing countries. The Commission was informed that in the main the food legislation of these countries was based either on British or French legislation but some progress had been made recently in drawing up national food laws in some countries. The Commission noted that this had apparently stimulated an increase in the membership of African countries in the Codex Alimentarius Commission from four to eight countries and again emphasized the importance of the participation of these countries in the work of the Commission. Such membership was also useful to establish contacts with the authorities responsible in these countries for health, sanitary and other matters connected with food legislation and to enable those authorities to receive useful information from FAO and WHO on the activities of the Commission. It was emphasized that membership did not involve any financial contribution additional to that which countries were already making to the Regular Programs and Budgets of both Organizations, and that participation in the work of the Commission could also be carried out by way of correspondence.

It was decided that a similar survey of food standards needs in Asian countries should be carried out.

With regard to Latin America, it was noted that Argentina had for the last 40 years a national code and that a Latin American Food Code has also been adopted by a number of the countries of this region. The Argentine delegate informed the Commission that a new edition of the Latin American Food Code would be issued shortly. The Commission agreed that in order to complete the picture of food standard needs in the main developing areas of the world, an appropriate survey should also be made for Latin America.

Progress on Other Standards

Also sent out for comments at step 6 were the standards for canned asparagus, canned pineapples, canned Pacific salmon, edible fats and oils, soya bean oil, maize oil, sesame seed oil, safflower oil, lard, rendered pork fat, premier jus, edible tallow, white sugar and powdered sugar. Cocoa products and chocolate were returned to the Committee at step 4. Mr. Graham Kermode, in behalf of the Secretariat, pointed out that there was a wide divergence of opinion between producing countries and importing countries, as well as manufacturers, as to processes. He said the proposed standards for cocoa products and chocolate were the most highly controversial

standards being considered by the Commission. Mr. Grange stated that the high degree of diversity of chocolate products might make it undesirable to have standards for all of them.

The Codex Committee on Food Additives reported that a definition of "food additives" would be discussed at its next session. The Codex Committee on Foods for Special Dietary Uses reported that it had concluded that its scope of activity included both special foods for certain categories of healthy persons and also dietary foods, the use of which was connected with morbid conditions of the human body.

Other Matters Considered

The Commission was informed by the Swiss delegation that it would be willing to assume the chairmanship of a Codex Committee on Soups and Broths. The significant expansion in international trade in soups and broths was noted by the Commission. However, it was pointed out that there are innumerable ingredients in soups and that in some countries there was a preponderance of dried soups, while in others canned soups were the favorites. It was also pointed out that new products such as frozen soups were gaining an increased importance. It was concluded that these products could not claim a high position, particularly as they were at present of little interest to developing countries. Mr. Grange pointed out that the United States had reservations about the advisability of any standards for soups outside of those relating to additive and labeling requirements. The delegation of Switzerland undertook to prepare a study on the regulations for soups and broths in the various countries and the importance of these products in world trade, in conjunction with the Secretariat. This paper will be distributed to governments for comment and will be reviewed at the next session.

The Commission also considered a paper prepared by the Secretariat on the subject of Codex standards for edible ices. It was reported that the Committee on Milk and Milk Products may consider standards for such products which contain milk ingredients at its next session. Mr. Grange reported that the United States felt that no standards for these products should be elaborated at this time. The Commission was generally of the opinion that on the basis of information presently available to it, international trade in edible ices did not appear to be such as to warrant consideration of Codex standards for these products.

The European Economic Community (EEC) reported that it now has in force standards for colors and preservatives, that the

standards for antioxidants will be issued soon, that it is working on food standards for additives and methods of analysis, and that drafts are being proposed for packaging materials and labeling of preserved or canned foods and dietetic foods.

Progress Made at Fifth Session

As indicated by the foregoing, while many disturbing problems were disclosed at this session, it appears on the other hand that much sound influence was brought to bear for the achievement not only of harmonization but also reasonable regulation as the basis for it. Intelligence, ability to give a little and the overriding requirement for agreement on standards prevailed in most instances over nationalistic or narrow-minded interests. Mr. Grange, his assistant, Mr. F. Robert Anderson, and all the other members of the United States Delegation worked faithfully and effectively to this end. They deserve the warm commendation of American industry.

Those desiring a more detailed report on this meeting may secure it by writing to:

United States FAO Inter-Agency
Sub-Committee on Codex Alimentarius
Agriculture Marketing Service
United States Department of Agriculture
Washington, D. C. 20250

[The End]

DR. GODDARD RESIGNS AS FDA CHIEF

Dr. James L. Goddard, Commissioner of the Food and Drug Administration for 28 months, resigned on May 21, 1968, effective July 1, 1968.

Dr. Goddard stated that he was retiring for personal reasons after more than 21 years in public service, which had been "deeply satisfying." HEW Secretary Wilbur Cohen accepted the resignation of "one of our finest public servants . . . with great reluctance."

Dr. Goddard, who is 45, will direct a regional office of EDP Technology, Inc., and specialize in the use of data processing and information systems in the area of medicine.

At press time, no successor had been announced.

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