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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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FDA's Intensified Drug Inspection Program (IDIP)

By ALFRED BARNARD

Mr. Barnard Is the Director of the Bureau of Regulatory Compliance of the Food and Drug Administration.

THE INTENSIFIED DRUG INSPECTION PROGRAM (IDIP) is one of the major compliance efforts currently underway by the Food and Drug Administration (FDA). It is also a major effort toward an effective blend of voluntary and regulatory compliance. The basic concept evolved from our previous experience in carrying out drug inspections. In the past, we carried out drug inspections largely as one-shot jobs. The inspector visited the plant and inspected for violations and evidence to prove the violations. He remained a relatively short time—too short a time to determine whether the plant could be expected to consistently operate in compliance. He either established an evidentiary basis for concluding that violations were occurring, in which case he terminated the inspection and hastened to report the facts to his superiors, or he remained long enough to conclude that the search for violations had reached the point of diminishing returns.

With the passage of the Kefauver-Harris Amendments, which included the requirement that drugs be manufactured in accordance with Current Good Manufacturing Practices, it became necessary to take another look at the way we were inspecting drug plants. There was mounting concern over the continued failure of many drug firms to bring their operations into accord with Current Good Manufacturing Practices, and over the continued incidence of subpotent and otherwise improperly compounded or improperly labeled drug preparations on the market. Drug recalls were increasing. It was obvious that some steps had to be taken to improve the situation.

Why the IDiP Was Chosen

Several options were open to FDA. We could have sought batch-by-batch certification authority, as now required for antibiotics and insulin. We are not sure, however, that batch-by-batch certification provides all the answers, and it is expensive besides. Another alternative was to seek licensing authority over drug manufacturing, requiring a manufacturer to demonstrate competence to produce individual products before a license to produce a drug would be granted.

A system of continuous inspection, in which all manufacturing operations would be under the watchful eye of a "resident" inspector, was another possibility in which the Department had an interest.

Because of the very high cost of these kinds of programs, either to Government or industry, or both, and, in some cases at least, the lack of statutory authority, we turned to a fourth alternative—the intensified inspection.

This concept envisions that a qualified inspector, or inspection team, will remain with a specific drug manufacturer on an essentially full-time basis until sufficient familiarity with the firm's operations has been acquired to provide reasonable assurance that the firm is operating in compliance, or to clearly identify the firm's shortcomings. As a matter of basic policy, problems are immediately called to top management's attention during the course of the inspection. Such advice and assistance as is appropriate is offered by the inspector, and, if necessary, by other members of the FDA District Office staff. The emphasis is on bringing about immediate voluntary compliance. On the other hand, the consumer is not deprived of the protection to which he is entitled since failure to bring about correction, whether willful or negligent, will, and in some cases already has, led us to such injunctive relief or other action by the appropriate U. S. District Court. The broad aim is to either bring about the production of legal drugs or a cessation of drug production.

There is another important feature of the program which relates directly to its Voluntary Compliance aspects. This is a pre-intensified-inspection conference where the District Director or his representative sits down with top management of the firm involved and discusses the procedures to be employed, the channels of communication, the reporting methods and all of the various details. We have found this procedure extremely helpful, both to us and to management.

Very few problems have come to our attention so far. One or two firms have expressed concern over the fact that the inspector stays around long enough to begin to learn some of the firm's more closely guarded manufacturing or production secrets and have asked for some kind of assurance that this important information will not be passed on to competitors. We are sympathetic toward this concern. We have pointed out, however, that our inspectors sign a statement upon entering the service and another upon leaving the service with respect to the restrictions on their use of any knowledge or information acquired during the course of their official duties, and also that Section 301(j) of the law provides criminal penalties for those who transgress these restrictions. It is also a fact that there has been no known incident of this kind in the 60-odd years since there has been a Federal food and drug law.

Data Subject to Modification

As you know, except for a few pilot inspections, the Intensified Inspection Program did not begin until July 1. During the first seven months of the program, we initiated 143 inspections of manufacturers of finished pharmaceuticals, and eight inspections of independent laboratories. So far, we have terminated 22 inspections of manufacturers of finished pharmaceuticals. Eighteen of these were terminated after we were able to conclude that the firms' operations were such as to provide a high degree of likelihood that their products will consistently comply with the law; four were terminated for reasons of noncompliance, with subsequent recourse to the Courts. You will note that the vast majority of the intensified inspections undertaken are still in progress—actually 129 out of 151 as of the first of February. Obviously, this is why it isn't yet feasible to develop any final evaluation of the program.

On the other hand, we do have enough data to enable us to begin to draw some general conclusions, subject to modification as we acquire additional experience. For example, it has already become quite obvious that the program has fostered a much better rapport, and much more effective communications, between industry and FDA. The dialogue which has evolved in many instances between the top management of the firm under inspection and the FDA District Office staff has proven most useful and helpful to both participants.

We in FDA have the impression that the industry as a whole has reacted very favorably to the intensified inspection approach. We

have no way of really knowing whether this impression reflects a good public relations job on the part of industry or whether this really is the true situation. We certainly hope the latter is the case.

Our experience in the program so far has not changed our view that serious inadequacies do exist in the production and marketing of prescription drugs. It is becoming apparent, however, from the inspections that these inadequacies are individual firm problems rather than across-the-board industry problems.

Specifically, we have encountered such widely diverse things as traffic in stolen drugs on the part of the president of one firm, the use of non-English speaking personnel in the production department of a firm whose production records are all in English and none of whose first line supervisors were bi-lingual; an employee who added the active ingredient to a batch, took a coffee break, returned and added it a second time; a capsule cleaning, polishing, and inspection machine which had numerous inaccessible areas where capsules could become lodged and subsequently dislodged to be combined with capsules of different products; serious discrepancies between theoretical and actual yield which are still under accountability study by the firm involved; insect infested raw materials, and the use of non-permitted colors. There are many other interesting examples that could be added to this list.

IDIP and PEV—Separate Evaluations

There is another relatively new FDA program which I would like to discuss briefly because it has caused some concern with industry. This is the Plant Evaluator, or so-called PEV, System. This program has been widely misunderstood and, in spite of my strong protestations on the subject, some of my very good friends in industry insist on either not hearing or disbelieving what FDA has to say on this subject.

The PEV System, in the first place, is an experiment. It was suggested to us by a firm of management consultants who worked with FDA over a 2-year period to assist us in developing better ways to do our job. In the last two or three years FDA's program emphasis has broadened from a basic law enforcement concept to a problem-solving orientation. As this has taken place, we have become more and more aware of the fact that we really don't know what our problems are in many instances. We have a wealth of information about individual firms but very little available information about

industries, changes which have taken place in industries, and the general compliance status of industry.

The purpose of the PEV System is to try to obtain some data which will be useful in this connection. We intend to compare practices in a given industry at some point in time with practices in the same industry at a subsequent point in time in order to measure what changes have taken place and, if possible, to relate these changes to measures taken by industry, by FDA, by state and local authorities, or perhaps as a result of other outside influences.

The PEV form for a given industry lists a number of things called key indicators. It seems this was an unfortunate choice of words because it lead a number of people to conclude that FDA had decided these were the "make or break" items in measuring the compliance status of a firm. Such is not the case.

We have said many times before, and I will say it again, that the PEV System is not intended in any sense as a measure of the compliance status of any firm. The PEV data are sent into headquarters separate and apart from the report of the inspection. The data sheets are not evaluated by the District. They are being incorporated into a computerized system here which, hopefully, will permit analyses of the data from several standpoints, none of which will be related to any individual firm.

We have had a number of complaints from various firms and some Congressmen that the "requirements" set forth in the PEVs are unrealistic and that they "will force firms out of business." There are *no* requirements in the PEVs. The PEVs simply identify various specific items which we intend to check throughout an industry from time to time to identify problem areas and to measure changing practices.

Some firms have urged that they be allowed to assist the inspector in completing the PEV answer sheet; some firms have even gone so far as to request that we not complete a PEV answer sheet with respect to them. As a matter of fact, instructions to our inspectors are to avoid completing any part of the PEV answer sheet in the plant or during the inspection specifically to avoid giving the impression that the sheet is some kind of compliance checklist. The inspector is instructed to bring back in his notes the necessary factual information and complete the PEV answer sheet at the office.

In the last few years, FDA has greatly improved its communications with regulated industry. I can well remember the time when,

had we initiated something like the PEV, it would have been highly confidential, and industry would have been told little or nothing about it. The present policy of FDA does not support this kind of an attitude. Therefore, when we decided to experiment with the PEV System we made this information available to industry and assured interested industry that we would not object to their having copies of PEVs, if they desired them.

But in informing industry that we were going to have our inspectors record some specific data during an inspection for later translation to a computerized study, we did not intend to create the basis for negotiations with industry about what data FDA should or should not collect and computerize for analysis. This is FDA's experiment and, obviously, we are the ones who must decide the kinds of data that are needed to carry it out. But let me reiterate that the PEV System is not now, and is not contemplated to become, an inspector's checklist or score card to measure the compliance status of any individual firm. I hope this eases the concerns some of you may have.

To return to the intensified inspection and its relation to the PEV, our present instructions call for the inspector to complete (in the office, as I said before) a PEV answer sheet at the start of an intensified inspection, and a second sheet at the termination of an intensified inspection. After we have pairs of PEVs from a statistically significant sample of the pharmaceutical manufacturing industry, we will take a look at these data, and then, and only then, in my opinion, will we be able to reach some conclusions as to whether the PEV System can yield meaningful information about the pharmaceutical industry as a whole.

Any valid information we are able to derive from the PEV System will be made freely available to any interested industry. I see no reason why such information should not serve as a basis for discussion between FDA and a particular industry about the significance and interpretation of PEV data. Such a dialogue could provide a basis for industry improvements, the development of more effective approaches by FDA, refinement and sophistication of the system itself.

To summarize very briefly then, we think the IDIP, as we see it now, is working well and we are favorably inclined toward continuation of the program, certainly until the entire industry has been covered. We have found significant pluses in the program for both industry, the consumer and FDA. **[The End]**

Drug, Device, Cosmetic?—Part I

by STEPHEN WEITZMAN

The author is the 1968-69 Food and Drug Law Institute Fellow in the Masters program in Trade Regulation at New York University School of Law. The author wishes to thank Franklin M. Depew and Frank T. Dierson for their continued assistance, instruction and guidance during the past year, without which this graduate program could not succeed.

ALTHOUGH THE FEDERAL FOOD, Drug and Cosmetic Act[1] has been on the statute books for thirty years, the federal courts have not until recently been called upon to examine and explain the definitions of the terms "drug", "device", and "cosmetic". Despite the sudden presence of several critical cases,[2] no exact delineation of the boundaries and overlap of these definitions has been made with logical and precise basis. Due to current advances in biomedical engineering, products never conceived of by the drafters of the statute will nevertheless have to be classified into these categories.

The Federal Food, Drug and Cosmetic Act was passed to protect "the public health" by regulating the preparation and dissemination of food, drugs, devices and cosmetics. The respective definitions of the classes of products are set forth in Section 201 of the Act as follows:

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) (1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United

[1] 21 U. S. C. 301-92 (1964).

[2] *AMP Incorporated v. John W. Gardner, HEW Secretary,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,192, 389 F. 2d 825 (CA-2, 1968), aff'g 275 F. Supp. 410 (DC NY, 1967), cert. denied, U. S. Sup. Ct., 1968. *U. S. v. An Article of Drug * * * Bacto-Unidisk * * *,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,231, (U. S. Sup. Ct., 1969), rev'g 392 F. 2d 21 (CA-6, 1968). *U. S. v. An Article * * * "Line Away, Temporary Wrinkle Smoother, Coty" * * *,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,201, 284 F. Supp. 107 (DC Del., 1968). *U. S. v. An Article * * * Sudden Change,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,229 (CA-2, 1969), rev'g 288 F. Supp. 29 (DC NY, 1968).

States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means instruments, apparatus, contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering appearance, and (2) articles intended for use as a component of any such articles; except that the term shall not include soap.

Under certain circumstances a drug may also be defined as a "new drug"[3] with appropriate consequences which will be explained shortly.

In most instances the Act prescribes similar regulatory structures for products classified as "drugs," "devices" or "cosmetics." The same sanctions, namely, criminal prosecution,[4] injunction,[5] and seizure,[6] may be invoked for introducing these products into interstate commerce or receiving them in interstate commerce if they are adulterated or misbranded. According to the Supreme Court in *United States v. Dotterweich*,[7] all persons who are responsible for the illegal transaction are criminally liable including the manufacturer, distributor, corporate officer, agent or employee, even though they had no direct part in the questioned transaction. The important distinction between the regulation of "drugs" and other categories is

[3] 21 U. S. C. 201 (p) The term "new drug" means—(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of use; or (2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

[4] 21 U. S. C. § 333. (Supp. I, 1965).

[5] See footnote 4, note 1, § 332.

[6] See footnote 4, § 334.

[7] 320 U. S. 277, 64 S. Ct. 134 (1943).

the requirement under Section 505[8] that "No person shall introduce or deliver into interstate commerce any new drug, unless an approval of . . ." a "new drug"[9] application "is effective with respect to such drug," and under Section 506 and 507 which require batch testing and certification of insulin and specific antibiotic drugs.[10]

The required new drug application (NDA) is a lengthy compilation of clinical and animal tests performed by the manufacturer to prove that his drug is both safe and effective.[11] The clinical testing and filing of an NDA involve the expenditure of a very considerable amount of money before the product is marketed.[12] This government approval, if secured, can come after many months or years.[13]

Because there are overlapping elements in the above definitions and because there are no precise guidelines, counsel is faced with a difficult classification problem each time a new product is developed which may fall within the scope of these definitions. Counsel may

[8] 21 U. S. C. § 355, and to a limited extent under § 357.

[9] The "New Drug" provisions present a method of ensuring that the public is protected against mistakes of science. (Christopher, *Cases and Materials on Food and Drug Law*, 429 (1966). The process of evaluating the effectiveness of a drug followed by the government has three steps: first, the benefit of the drug is determined; second, the risk; third, it weighs the relative values. (See Sen. Rep. 1744, 87th Cong., 2d Sess. 14 (1962). However: "The judgments of society are not necessarily consistent with scientific facts. Neither are they always logical. They can be and sometimes are, arbitrary. Even so, neither the executive nor the legislative branches of government can long ignore them. If it should become the overwhelming public view that society should drastically limit the risk no matter how much good a drug can do, then we would be forced to remove from the market many drugs whose good far outweighs their harm. Carried too far, such developments would seriously impede the progress of medicine." (Statement of George P. Larrick, former Commissioner of Food and Drugs, during Hearings on Drug Safety Before Subcommittee of Committee on Government Operations, H. R. 88th Cong. 2d Sess. 149-154 (1964). Christopher, 448-451.)

[10] § 337 of the Act provides that no drug containing an antibiotic may be marketed unless the batch has been certified.

[11] The Kefauver-Harris Amendments of 1962, 76 Stat. 780, changed the definition of "new drugs" to include those drugs not generally recognized as both safe and *effective* by qualified experts. This amendment was passed as a direct result of the Thalidomide tragedy. See, Toulmin, *The Law of Food, Drugs and Cosmetics*, § 53.1 (2 ed. 1963) and Sen. Rep. 1744, 87th Cong., 2d Sess. (1962).

[12] According to Happold, *Medicine at Risk*, 186 (1967) the outlay on toxicity tests and clinical trials to satisfy the FDA on antibiotics was in the order of $210,000, plus the cost of administering the work

[13] See 21 FOOD DRUG COSMETIC LAW JOURNAL 21 (January, 1966). 22 FOOD DRUG COSMETIC LAW JOURNAL, 382 (July, 1967). Since 1962 the number of NDAs and the percentage approved have declined while the average processing time has increased.

(Continued on next page.)

seek the assistance of the Food and Drug Administration (FDA) when he is unsure whether the product may be classified as a drug, but he is warned that he will automatically be told that the product is a drug.[14] If he fails to consult the FDA and independently determines that the product is not a drug, his client faces the hazard of marketing a product which may later be classified by the FDA as a drug and possibly a "new drug" which will not have been precleared by the agency and is therefore marketed in violation of the statute.

Choosing to avoid the FDA, therefore, may later place counsel in the unenviable position of having his client face seizure, injunction or even a criminal action in courts which tend to favor the Government's point of view.[15] For "the Food, Drug, and Cosmetic Act is to be liberally construed to carry out its statutory purpose to protect the public."[16]

Several approaches in statutory interpretation may be used in classifying the new product under the definitions of this Act. Each approach, because of some fundamental premise, has a predetermined

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(Footnote 13 continued.)

	FDA FIGURES Applications		1966 Food Drug Cosm. L. J.		P.M.A. Figures** No. of NDAs	
Year	Handled	Approvals	Appls.	Appr.	in survey	Av. days
1958	353	208			153	102
1959	375	231	369	230	172	106
1960	321	165			127	136
1961	276	133			98	191
1963	189	67	179	67	61	327
1964			160	84		
1965			203	53		

** *Pharmaceutical Manufacturers Association Bulletin* 64-6, March 12, 1964: see 22 FOOD DRUG COSMETIC LAW JOURNAL 360 (June, 1967).

In the *Journal of New Drugs*, March-April, 1964, Mr. Larrick, former Commissioner of the FDA discussed his review of the "chronology of a particular new drug application that contained over nine volumes and about 4,000 pages of data. In all it took the FDA 195 days to review and evaluate this application. During this time, twenty-nine of our professional staff representing eleven different units participated, as did six outside consultants. Two special inspections of the drug maker's facilities were necessary, and analytical tests had to be made by two of our district laboratories. Our Bureau of Medicine held three special staff conferences plus another conference with the manufacturer. During the same time we had to handle nineteen contacts made by the sponsor. This particular case is not unusual. The FDA in fiscal year ending 1963 alone received 1,100 new drug applications. True some were shorter and required less time to process, but, on the other hand, many were even more complicated and required an even greater amount of time and effort." Happold, *Medicine at Risk* 186 (1967).

[14] Compare 21 FOOD DRUG COSMETIC LAW JOURNAL 26 (January, 1966).

[15] Compare 22 FOOD DRUG COSMETIC LAW JOURNAL 382-4 (July, 1967).

[16] *United States v. Urbeteit*, 335 U. S. 355, 69 S. Ct. 112 (1948) and others.

result.[17] In order properly to interpret this statute, the words of the definitions must be reconciled with the legislative history of the Act including the concrete examples given to illustrate the nature of the products within the classifications. Only upon full consideration of the language, the purpose and the legislative history of the Act can a proper judgment be rendered.

In order not to eliminate any material which may possibly be cited to rebut the position taken in this article, a comprehensive review of the legislative history will be provided with as much original text as possible.

The Legislative History

> ...(W)hat is more to the point as we are in this case interpreting legislative enactment, it is our duty to try to discover and carry out the legislative purpose, not to inject our own notions of desirable policy;...[18]

In the decisions by the courts construing the definition, there is no complete analysis of the legislative history which supported its position and omitted other relevant parts which contradicted it. The following analysis of the history is more complete.

The Pure Food and Drug Act of 1906 was the first comprehensive measure to control fraud in food and medicine. As enacted in 1906 the term "drug" was defined as:[19]

> ... all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease in man or other animals.

This definition limited the products classified as drugs to those used explicitly for medicinal purposes.[20]

In April, 1933, prior to the introduction of the first major revision of the Act, the Department of Agriculture held a series of conferences on the problems presented because of deficiencies in the 1906 Act.

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[17] Llewellyn, "Remarks on the Theory of Appellate Decisions and the Rules of Canons About How Statutes are to be Construed," 3 *Vanderbilt Law Review* 395, 398-406.

[18] *Ingo v. Koch*, 127 F 2d 667 at 668 (2d Cir. 1942).

[19] Dunn, *Federal Food, Drug and Cosmetic Act—A Statement of Its Legislative Record* 1338 (1939) (hereinafter, Dunn).

[20] As early as 1917 the Chief of the Bureau of Chemistry, then in charge of the administration of the 1906 Act reported that among its conspicuous limitations were: ". . . the limitations placed upon the term "drug" by the definition which render it difficult to control injurious cosmetics, fraudulent mechanical devices used for therapeutic purposes, as well as fraudulent remedies for obesity and leanness." 1917 Annual Report, reprinted in *Federal Food, Drug and Cosmetic Law—Administrative Reports*, 1907-1949, 355 at 370 (1951).

Suggestions were made to amend the definition of the term "drug" and thereby enlarge the scope of the statute to include:

1. Any mechanical article or device or apparatus which is recommended for medicinal use in order to prevent deceit in its sale.

2. Obesity, beauty preparations and cosmetics.[21]

Another most notable defect was the failure of the 1906 Act to cover cosmetics except where the claims made for the cosmetic brought it within the "drug" definition. Even this protection would not have existed but for an early amendment to the 1906 Act.[22] The conference rejected an approach which would have included all cosmetics in the term "drug," in favor of adding a separate definition for "cosmetics."[23]

Consideration of the original bills[24]

The deficiencies in the scope of the 1906 Act were to be remedied by the following new definitions:[25]

(a) The term "food" includes all substances and preparations used for, or entering into the composition of, food, drink, confectionery, or condiment for man or other animals.

(b) The term "drug" includes (1) all substances and preparations recognized in the United States Pharmacopoeia or National Formulary or supplements thereto; and (2) all substances, preparations, and devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations, other than food, and all devices, intended to affect the structure or any function of the body of man or other animals.

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[21] A further amendment was proposed, to make articles listed in the United States Pharmacopoeia and National Formulary drugs, subject either to the approval or promulgation of the Secretary of Agriculture. Dunn, 1033-37.

[22] In *United States v. Johnson*, 221 U. S. 488 (1911) Mr. Justice Holmes held that the 1906 definition of the term "misbranded" was insufficient to prevent the manufacturer from making false claims as to therapeutic value on the packaging of the article. The claim in this case was that the product cured cancer. As a consequence of this decision, the misbranding definition was amended to include false and fraudulent statements concerning therapeutic effects. Shelby Amendment [37 Stat. 416, (1912)].

[23] "In my reference to a cosmetic amendment of the act I did not recommend that the term 'drug' be revised to include cosmetics. I only intended to suggest that cosmetics be included in the act for regulatory purposes along with foods and drugs." Comment of Charles W. Dunn, 1036.

[24] Briefly the legislative record is as follows: S. 1944, 73d Cong. 1st and 2d Sess. (1933-34)—died in Senate Committee; S. 2000, 73d Cong. 2d Sess. (1934)—died in Senate Committee; S. 2800, 73d Cong. 2d Sess. (1934)—died on Senate Calendar; S. 5, 74th Cong. 1st and 2d Sess. (1935-36)—passed in Senate, defeated in House; S. 5, 75th Cong. 1st and 3d Sess. (1935-36)—was enacted. The two preclearance bills: S. 3073, 75th Cong. 2d and 3d Sess. (1937-38)—supplemental to S. 5; H. R. 9341, 75th Cong. 3d Sess. (1938)—companion to S. 3073. Dunn, 23.

[25] Dunn, 37.

(c) The term "cosmetic" includes all substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of, the person. Except as indicated in paragraph (b) (3) of this section, the definitions of food, drug, and cosmetic shall not be construed as mutually exclusive.

These definitions plugged loopholes in the old Act and preserved as much as possible the language of the 1906 Act and the effect of appellate decisions made from 1906 to 1933.[26]

Senator Royal S. Copeland, a homeopathic physician,[27] and the sponsor of the bills revising the Food and Drug Act, inserted into the record the following memorandum indicating differences between the Senate bill and the existing law:[28]

	S. 1944	Present Law
Section 1.	Title	Definition of drug (in 1906 Act) does not include therapeutic devices, or drugs or devices intended to affect nonpathologic conditions of the body. Cosmetics and advertisements not defined.
Section 2.	Definition of food, drug, cosmetic, advertisement and other terms used in bill.	

In the Annual Report of 1933 the Chief of the Food and Drug Administration, Walter G. Campbell, principal draftsman of the bill,[29] explained how the proposed revision of the 1906 Act remedied prior deficiencies.[30]

At hearings held on S. 1944 before the Senate Committee on Commerce, Mr. Campbell compared the old and new definitions. He briefly reviewed the scope of the first two subsections, adapted from the 1906 definition and named some of the products intended to be covered within the term "device," included within the term "drug," such as sutures, surgical dressings, trusses, and other mechanical appliances which might be employed to treat disease.[31] Mr. Campbell stated:

The third portion of the definition of the term drugs, all substances and preparations, other than food, and all devices intended to affect the structure or any function of the body of man or other animal, is admittedly an inclusive, a wide definition.

In Mr. Campbell's opinion, this portion of the definition was constructed to regulate products which "cannot be alleged to be

[26] See statement of Henry A. Wallace, Secretary of Agriculture, Hearings of the S. Commerce Committee, on S. 1944, 73d Cong. 1st Sess., Dunn, 1048.

[27] 13 *J. Pub. L.* 197, 200.

[28] Dunn, 30.

[29] See footnote 25, statement of Henry A. Wallace, Dunn, 1049.

[30] *Federal Food, Drug and Cosmetic Law—Administrative Reports*, 1907-1949, at 799-800 (1951), and Dunn, 25-27.

[31] Dunn, 1053.

treatments for diseased conditions." Included in this class were anti-fat remedies; devices used to correct physiological or anatomical defects that may not in themselves be diseases, such as nose straighteners; "most of them are pure frauds; many of them if used will produce physical harm."[32]

The bill died in committee and was superseded by S. 2000 in which the scope of the proposed definition of "drug" also included articles in the Homeopathic Pharmacopoeia.[33] The new bill deleted the clause in the cosmetic definition which stated that the product definitions were not mutually exclusive.[34] This bill was superseded by S. 2800,[35] a revision of the former bills. No material change was made in the proposed definition of "drug."[36]

Mr. Campbell again explained the meaning of the term "drug" to the Senate Committee at hearings on S. 2800,[37] partly in response to a complaint that the definition could include preparations such as whisky when used for other than medical purposes, and the recommendation that the section which made preparations listed in the pharmacopoeias as drugs be limited to products intended for medical use. The definition would then have read:

> The term "drug" for the purpose of this Act, and not to regulate the practice of medicine, includes (1) all substances and preparations intended for medical use recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia, or National Formulary...

Mr. Campbell rejected this limitation because of the added burden of proof he claimed would be imposed in a criminal action requiring the Government to show that the allegedly violative product was intended to be sold as a medicine. He asserted that without this amendment the showing that the product was marketed by a pharmacist or retail druggist would be sufficient circumstantial proof that the product was a drug. Whether or not this argument was in fact correct, the committee did not accept the proposed amendment.[38]

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[32] Dunn, 1053-54.

[33] Dunn, 52.

[34] See definitions at footnote 24, and explanation at footnote 39.

[35] Dunn, 71.

[36] The term "drug" for the purposes of this Act and not to regulate the legalized practice of the healing art, includes (1) all substances and preparations recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, or National Formulary or supplements thereto; and (2) all substances, preparations, devices intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations, other than food, and all devices intended to affect the structure or any function of the body. Dunn, 72.

[37] Hearings before the S. Committee on Commerce on S. 2800, 73rd Cong. (1934) Dunn, 1124-1126.

[38] Compare S. 2800, Calendar No. 520, Dunn, 93.

Mr. Campbell continued his explanation, directing his attention to the phrase "all substances and preparations other than food, and all devices intended to affect the structure or any function of the body." He stated that one purpose of this phrase was to cover preparations which are neither "drugs" nor "food" under the 1906 definition, for example, slenderizing compounds. These products escaped the statute because obesity was not a disease and only preparations intended to cure or treat disease were covered. He referred to the product "Marmola" described previously by Senator Copeland as "a powerful drug," and said that it should be used only under the direction of a physician.[39]

Examples of the products included in the phrase "devices intended to affect the structure and function of the body" were enumerated as follows:[40]

> There are innumerable devices, Senator. The present law does not cover devices. As a matter of fact, it has been held, at least administratively, that it did not cover such products as sutures used in sewing up wounds from surgical operations. "Devices" would include trusses. It would include a great many products that are advocated for changing the physical appearance of a person. Heightners.

Mr. Campbell also told another senator that a belt recommended by Dr. Copeland to strap his sprained back was a "device" and therefore a drug under the proposed definition.

After completion of the hearings, the majority of the committee in its report submitted with the proposed bill explained that the bill expanded the drug definition to embrace substances and preparations in the Homeopathic Pharmacopoeia; devices intended for the cure,

[39] "Let me tell you the purposes of that. There are products on the market now that escape control either under the definition of food or under the definition of drugs in the present act such as slenderizing products, reducing products. Obesity is not itself a disease in all instances and products advocated and sold for the treatment of obesity, as a matter of fact, are not always subject to the terms of this act.

In regard to slenderizing products, it is fashionable on the part of the girls or it has been, to retain a sylph-like slender figure. They are victims, in such circumstances, of the sale of products that are capable of really injuring their health. There was one such article handled by the Federal Trade Commission, Marmola, to which Senator Copeland has referred, in the testimony of Judge Davis, 2 or 3 days ago. That product is a powerful drug. It ought not to be administered except under the direction of physicians. Under the power of this law there was absolutely no ground by which we could claim jurisdiction. Now, the purpose of that paragraph (3) is to give jurisdiction over that product. It certainly ought to be subject to control, just as definitely, and perhaps more so, than a great many articles of food and drugs." Dunn, 1126.

[40] Dunn, 1126.

mitigation or treatment of disease; substances and preparations, other than food, intended to affect the structure or any function of the body. The general purpose was to protect the consumer with a broader health law.[41]

The report added that the definition of cosmetic, food and drug were not to be read as mutually exclusive. A positive statement to that effect in the statute was deemed superfluous since no court in thirty years under the old law held the definitions to be exclusive, and this despite the fact that actions against unsanitary foods for which false therapeutic claims were made have successfully alleged that the product was both a misbranded drug and adulterated food. "The use to which an article is put determines the category into which it will fall. If it is used as a food, it will come within the definition of food and none other."[42] In addition to actual use, intended use as expressed, for example, in representations made for the product were determinative of classification.

Despite the statement that the classes were not mutually exclusive, this report indicates within the third subsection, "substances and preparations, other than food, and devices . . . ." These were two distinct classes of products. Senator Copeland in his remarks summarizing the report gave separate examples for these classifications:[43]

> The present law (1906 Act) defines drugs as substances or mixtures of substances intended to be used for the cure, mitigation, or prevention of disease. This narrow definition permits escape from legal control of all therapeutic or curative devices like electric belts, for example. It also permits the escape of preparations which are intended to alter the structure or some function of the body, as for example, preparations intended to reduce excessive weight.

These examples are not an exclusive list of the products covered. In his next sentence the Senator added, "[t]here are many worthless and some dangerous devices and preparations falling within these classifications. S. 2800 contains ample authority to control them." The Senator then listed a number of worthless apparatus sold to cure appendicitis, tuberculosis and diabetes.[44]

Second Phase—Food, Drug, Device, Cosmetic

The next phase of the legislative history concerns itself with the enlargement of the specific categories of products. In the first phase "drugs" included "devices," but in the second phase a separate parallel definition for devices was included. In addition, the statement that the definitions of drug, food, and cosmetic were not mutually

[41] Dunn, 110-112.
[42] Dunn, 111.
[43] Dunn, 162.
[44] Dunn, 162-163.

exclusive was not expanded to include devices. In fact, a clause was ultimately added to the drug definition stating that the drug classification does not include devices. The legislative record for this phase is as follows:

S. 2800 was not passed, but was reintroduced in the subsequent session as S. 5 in which the definitions of the terms "drug" and "cosmetic" were unchanged.[45] The bill was referred to committee for hearings[46] at which Mr. Campbell was again called to testify. In response to criticism of the construction and broad scope of the definition of "drug," Mr. Campbell made the following statement:[47]

> Definitions—There is a universal recognition that the definition of the term "drug" in the third subdivision is inclusive. This fact was admitted in the hearing on S. 1944. To provide for jurisdiction over innumerable devices to which therapeutic virtues are ascribed, it will be necessary either to operate under the definition of this character, as incongruous as it is, or set up, as proposed by one witness, an independent paragraph relating to therapeutic devices.

Subsequent to the hearing an awkward debate ensued between Senators Copeland and Clark.[48] The Senators did not address themselves to the same issues during the course of their exchange. Senator Copeland, who had the floor, was explaining his reasons for amending the bill by inserting into the third subsection of the "drug" definition the word "diagnosis" before the word "cure," so that the term "drug" would include devices used for the diagnosis of disease.[49] Senator Clark interrupted by objecting to the inclusion of solely mechanical devices within the term "drug" because of the apparent incongruity of terms:

> MR. CLARK: Mr. President, I should like to ask the Senator from New York how he can reconcile the language of this section and the language of the amendment with the common, ordinary acceptation of the English language. In other words, here he says it is proper to describe as a drug "all substances, preparations, and devices intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." In other words, if a man has invented a shoulder brace, a purely mechanical device, which he claims will straighten a man's shoulders and expand his chest and make for his health, according to the definition contained in this paragraph it has to be described as a drug and treated in law as a drug.
>
> I should like to ask the Senator from New York to justify any such misuse of common, ordinary English terms.

Senator Copeland briefly answered Senator Clark by indicating that he had no objection to the separation of the terms "drug" and

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[45] Dunn, 192.

[46] Dunn, 1213.

[47] Dunn, 1223.

[48] Dunn, 286-300.

[49] a. The amended section would read as follows: Sec. 201 . . . (b) the term "drug" . . . (2) all substances . . . . intended for use in the *diagnosis*, cure, mitigation . . . Dunn, 214.

"devices." Senator Copeland then resumed his speech about the dangers of diagnostic devices.

MR. COPELAND: The Senator from New York would have no objection to the proposal about the particular devices mentioned by the Senator. But there are on the market a great many devices which are offered for use, and citizens are exploited believing that they can be cured of all sorts of ailments by the use of them. For example, there is such a thing as a radium belt carrying a disk alleged to contain radium; it is claimed that if the Senator from Missouri should wear that belt, he would never have appendicitis or gall-bladder disease or perhaps any other ailment.

Senator Clark was not satisfied with the answer given by Senator Copeland and therefore reiterated his point:

MR. CLARK: The language the Senator from New York has employed in this bill is broad enough to cover any device which the Food and Drug Bureau chooses to take jurisdiction. The point I am making is that if the devices ought to be outlawed, they ought to be outlawed, and I have no objection to that; but to maintain that a purely mechanical device is a drug and to be treated as a drug in law and in logic and in lexicography is a palpable absurdity, in my opinion...

Speaking for myself alone, I have no disposition to attack every word in the bill; but we are legislating on a very important matter. As I see it, what the Senator from New York is doing in this particular case is the same thing as if the Congress of the United States should attempt to say by law that calling a sheep's tail a leg would make it a leg. In other words, the Senator from New York in this language is attempting to define a wholly mechanical device as a drug. I say it is bad legislation; that if he desires to legislate against these mechanical devices he ought to do it in the open instead of by indirection and attempting to define as a drug something which palpably is not a drug.

Without replying to Senator Clark's remarks which were again not addressed to the amendment at issue, Senator Copeland explained the purpose of inserting the word "diagnosis":

MR. COPELAND: Mr. President, I desire to state the effect of this amendment.

There are on the market certain electrical devices. A man takes hold of the handles of the machine, and the indicator spins around. It stops at "appendicitis," or it stops at "meningitis"... Such a device is manifestly a fraud upon society.

That is what the amendment (diagnosis) is designed to deal with...[50]

After a brief recess Senator Copeland once again took the floor and summarized the position of the majority of the Senate Commerce Committee on the "diagnosis" amendment.

Mr. President, before the recess we were discussing page 2 of the bill, specifically the insertion of the word "diagnosis," on line 12, but in general the whole of the subsection, subsection (b). In our committee hearings we have had before us witnesses who made the same suggestion which has been made here by the Senator from Missouri (Mr. Clark); it seemed more or less absurd

[50] Dunn, 289.

to include in a food and drug bill various "devices" which were intended for the use in cure and treatment of disease. Those matters were considered at length in the public hearings, and it was the consensus that there was no better way than to include in this subparagraph these various devices.

If the Senator will read the first line of subparagraph (b)—that is, line 5 of page 2 of the bill—it will be seen that it says—The term "drug"—and the word drug is put in quotation marks—for the purpose of this act shall be so-and-so.

Because of the consensus of the evidence, it was deemed wise to leave this subsection as written.

The immediate question before us does not relate to the whole subsection. It relates merely to one matter of including the prohibition against devices and the word "diagnosis"...

The sole purpose of the word "diagnosis" in this subsection was to prohibit the use of the devices which are fraudulent on their face.[51]

The further remarks of Senator Clark[52] were not answered at this time, but his position was not ignored. In part as a result of Senator Clark's objections, the committee revised the definition of "drug" by removing devices from that definition and inserting a parallel definition defining devices in the same descriptive terms of usage:[53]

(g) (1) The term "drug"... includes (1) all substances and preparations recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) all substances and preparations intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations other than food and cosmetics intended to affect the structure or any function of the body.

(h) The term "device"... includes all devices, instruments, apparatus, and contrivances, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body.

The statement made in prior reports that the products were not mutually exclusive[54] was no longer entirely true. Nor was it any longer true that the products were classified solely on the basis of their use or intended use. The definitions were provided for classifying a product on the basis of its inherent nature. It is also interesting to note that although the diagnosis amendment was proposed to cover diagnostic devices, the term "diagnosis" remained in the drug definition.[55]

The Senate also amended the definition of the term "cosmetic" to exclude ordinary toilet and household soaps.[56] The scope of the definition was explained in the committee report submitted with the bill:

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[51] Dunn, 295-6.
[52] Dunn, 296.
[53] Dunn, 496.
[54] Compare Dunn, 111.
[55] Dunn, 496.
[56] Dunn, 24.

While the definition of the term "cosmetic" does not include devices, it is drawn in broad terms to include all substances and preparations, other than ordinary toilet or household soap intended for cleansing, or altering the appearance of, or promoting the attractiveness of the person. Cosmetics may be used externally, orificially, or even internally as in the case of the use of arsenic for clearing of complexion. The definition therefore must be sufficiently broad to cover potential abuses no matter how the substance or preparation is used.

The report also noted that soaps for which claims were made concerning disease would be "drugs" and regulated accordingly.[57]

The House Acts

This bill was referred to the House Committee on Interstate and Foreign Commerce, and hearings were again held on S. 5 together with H. R. 8805, H. R. 8941, and H. R. 6906.[58] Mr. Campbell again testified, this time explaining the new change adopted in the Senate.

The purpose of the third subdivision is to provide for "devices." Originally, this definition of "drugs" also included devices, such as mechanical appliances and contraptions which are to be found without number. But the incongruity of classifying certain devices, such as the electric belt, therapeutic lamps, and so forth, as drugs was pointed out by the Senate in the last consideration of the bill. They felt it proper to provide an independent definition of "devices"...[59]

At the same set of hearings, Dr. Woodward, Legislative Counsel of The American Medical Association, testified to the meaning of the term "device."

The term is broad enough to include—well, we will say trusses. I would say it is broad enough to include eyeglasses, checking up on the lenses; and clinical thermometers, possibly; *catgut used in surgical work; surgical instruments;* particularly, however, electrical devices, ultra-violet ray devices, and things of that sort; electrical belts, and a thousand and one things that are sold at the present time without any regulation at all and that are utterly fraudulent.[60] [Emphasis added.]

Dr. Woodward's testimony in no way conflicted with the statements and product category designations previously mentioned by Mr. Campbell and Senator Copeland.

The House Report[61] named the types of products actually examined which constituted abuses of the consumer's health and pocketbook against which there was either no protection or ineffective protection:[62]

Worthless drugs [presumably within the phrase "substances and preparations intended for cure"...etc.];

[57] Dunn, 239.
[58] Dunn, 1235, July and August, 1935.
[59] Dunn, 1247.
[60] Hearings, see footnote 53 at page 319.
[61] Dunn, 550.
[62] Dunn, 552.

[P]owerful drugs truthfully labelled, but bearing inadequate directions for use [substances and preparations in the pharmacopoeias or substances and preparations not listed but intended for cure, etc.];
Deadly drugs intended for reducing purposes . . . [substances and preparations intended to affect the structure or any function of the body];
Dangerous and worthless therapeutic devices [both devices intended for cure, etc., and intended to affect the structure or any function of the body];
Cosmetics that have caused deaths, blindness, and other body injury.

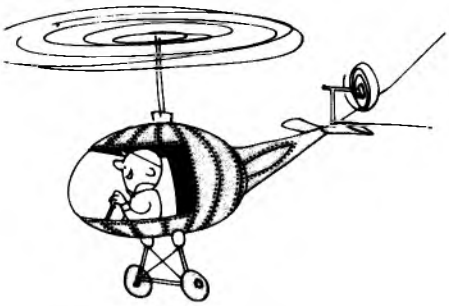
Like the Senate version of the bill, the principal differences between the House bill and the old law[63] was the inclusion of therapeutic devices and, in addition, drugs intended for diagnosing illness or for remedying underweight or overweight, or otherwise affecting the bodily structure or function.

The House then debated the measure. The first speaker, Mr. Chapman of the Committee on Interstate and Foreign Commerce, outlined the accomplishments of the revision,[64] pointing out especially the inclusion of cosmetics. He also mentioned those products previously discussed in the Senate which escaped coverage under the old act, such as deadly drugs intended for reducing purposes or drugs with instructions calling for excessive doses; dangerous drugs intended to affect the structure or the function of the body; dangerous and worthless therapeutic devices; and cosmetics that caused death, blindness and other bodily injury.

There was no disagreement in Senate and House versions over the definition sections. However the two houses disagreed upon which agency, the Federal Trade Commission (FTC) or the FDA, would enforce proposed provisions against false advertising.[65] S. 5 died because of the failure of the Senate and House to reach an agreement. The bill was succeeded in the next session by a revision which received the same designation, S. 5. Immaterial amendments were subsequently made to the drug, device and cosmetic definitions.[66]

The Senate passed its version giving jurisdiction over false advertising to the FDA[67] and referred the bill to the House in March, 1937.[68] About the same time the Senate passed a bill amending the Federal Trade Commission Act, S. 1077.[69] The House revised the Senate version of S. 1077, March 30, 1937, giving the FTC control over the advertising of drugs, devices and cosmetics. Of necessity

[63] Dunn, 553.
[64] Dunn, 571-2, 577-8.
[65] Dunn, 598.
[66] Dunn, 658, see also 696.
[67] Dunn, 658-659.
[68] Dunn, 751.
[69] Dunn, Wheeler Lea Act 131, (1938) [hereafter Dunn WLA] 75th Cong., 1st Sess. 1937.



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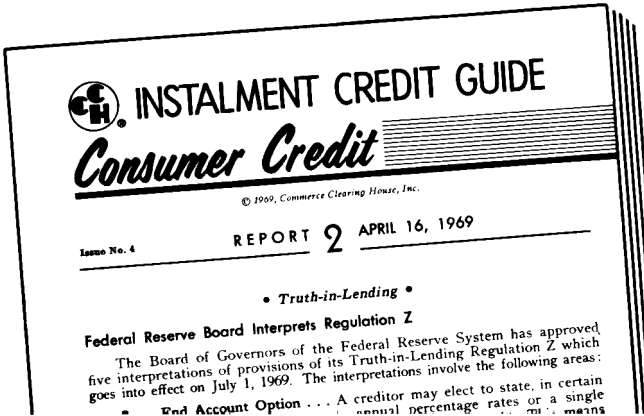

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• *Truth-in-Lending* •

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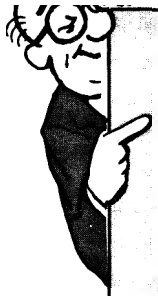

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the House version had a separate glossary of terms in which drug, device and cosmetic were defined. When S. 1077 was first introduced in the House, the definitions were the same as those in S. 5. The version of S. 1077 which finally passed changed the definitions by substituting the word "article" for "substances and preparations" in describing drugs, and inserting the phrase "instruments, apparatus and contrivances" in place of "device"; and adding a phrase specifically excluding devices, "their components, parts or accessories" from the term "drug." The report of the Committee of the Whole House described these new definition sections:[70]

> Speaking generally, "devices" within the terms of the Act means instruments, apparatus and contrivances intended for the use in cure or treatment of disease. "Devices" are included within the terms of the bill because of their close association with drugs as a means for treatment of physical ills.
>
> "Cosmetics" are brought within the meaning of the bill because in many instances cosmetics are injurious to health and produce physical injuries to health and produce physical injuries to the body.

During the same period the House Committee on Interstate Commerce revised S. 5 and adopted the definitions from its version of S. 1077. The bill S. 5 was reported in the Congressional Record August 25, 1937:[71]

> (g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts or accessories.
>
> (h) The term "device" (except when used in paragraph (n) of this section and in sections 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.
>
> (i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

In the report submitted with S. 5 Union Calendar No. 770, April 14, 1937, eight months later no apparent importance was attached to the substitution of "article" for the phrase "substances and prepara-

[70] See footnote 69 at 163-4, 170.

[71] Dunn, 752-753.

tions."[72] The report of the House Committee described the principal differences with the old act in the identical language used by Mr. Chapman in his description of the bill before the word "article" was substituted. The report further ascribed the amendments made in the definitions to a desire to conform to the Food and Drug Act definitions and to the definitions enacted in the Federal Trade Commission Act.[73]

The third phase: Critical differences: New Drug Preclearance

Until 1937 the bills provided very similar modes of regulation for all classes of products.

While Congress was considering the legislation, the sulfa drugs, sulfanilamide and sulfo-amide, were discovered.[74] This was a major advance in chemotherapy and in combating bacterial diseases. The two sulfa drugs were usually found in powder form and, because the powder was unpalatable to some people, a suitable solvent was sought in which to dissolve the powder. In October, 1937, headlines in the nation broke the news of a mounting death toll—over 100—from Elixir Sulfanilamide. This medicine, a combination of liquid ethylene glycol (commonly used as antifreeze) and powdered sulfanilamide, was never tested except for fragrance and taste, despite the fact that there was literature suggesting the toxicity of the carrier alone. Soon after the Congress became aware of the problem, it ordered an investigation.[75] The report delivered to Congress revealed that through the diligent efforts of the Food and Drug Administration, 228 gallons and two pints out of 240 gallons sold were destroyed, collected for laboratory samples or wasted. The charge on which the agency seized the goods was that they were misbranded because "Elixir" connoted alcohol and there was no alcohol in the preparation. Had the term "Elixir" not been used, the Government might not have been able to act against the allegedly misbranded article. Unfortunately, close to one hundred people did die.

In response to the disaster, the Department of Agriculture prepared legislation[76] to supplement the bill then pending, S. 5. The

[72] See H. Rep. No. 2139, 75th Cong., 3d Sess., April 14, 1938; Dunn 816-817. Compare, at footnote 59, for identical language where the definition of drug was "substances and preparations."

[73] Dunn, 817.

[74] See Report of Secretary of Agriculture on *Deaths Due to Elixir Sulfanilamide Massengill*, S. Doc. 124, 75th Cong., 2d Sess.

[75] See footnote 74, prepared in response to requests in H. Res. 352 and S. Res. 194, 75th Congress, 2d Sess. (1937).

[76] S. 3073, 75th Cong. 2d and 3d

(Continued on next page.)

purpose of the new legislation was to prevent repetition of the tragic experience[77] by requiring that new drugs which were "not generally recognized as safe for use in the dosage . . . frequency and duration prescribed, recommended, or suggested . . .", should not be marketed unless the Secretary finds the drug is safe for use.

The House version of the preclearance bill was submitted in H. R. 9341, 75th Congress, 3d Session (1938).[78] The preamble of the bill paralleled the Senate version,[79] but the body contained its own glossary in which the term "drug" was defined for purposes of this bill as inclusive of all articles for use in diagnosis, cure, treatment, mitigation, prevention of disease in man or animals and articles other than food which affect the structure or function of the body. The House version of the bill did not separately define devices and would have included all devices within the definition of the drug. Had this

(Footnote 76 continued.)
Sess., Companion in H. R. 9341, a revision of the department's recommendation. In the preliminary remarks on S. 3073, Senator Copeland declared: "Mr. President, it will be recalled that, because of the great number of deaths resulting from the administration of elixir of sulfanilamide, the Senate requested the Department of Agriculture to submit a report. That report has been submitted, and in accordance with the recommendations, I ask consent to introduce a bill to safeguard the public health as menaced by such poisons. The Bill is known as S. 3073. . . ." 82 Cong. Rec. 847-8 (1937). The preamble to the bill was as follows: *"Be it enacted . . .* That (a) in order to safeguard the public health against the distribution of drugs which have not become generally recognized as safe for use, no person shall introduce or deliver for introduction into interstate commerce any drug, composed in whole or in part, of any substance or combination of substances, which substance or combination is not generally recognized as safe for use in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling thereof, unless the packer of such drug holds a notice of a finding by the Secretary that such drug is not unsafe for use." Dunn 1018.

[77] MR. COPELAND. "The bill was introduced at a time when a large number of deaths occurred throughout the country from the sale of the elixir of which I have spoken. It developed that there was no means of protection, through the Public Health Service or the Bureau of Food and Drugs, to make certain that new preparations were given proper examination in order to insure that they were safe for human consumption. That is the purpose of the bill. . . ." Dunn, 1021.

[78] Dunn, 1023.

[79] *"Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That in order to safeguard the public health against the distribution of drugs which have not become generally recognized as safe for use, no person shall introduce or deliver for introduction into interstate commerce any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, unless such person holds a certificate issued by the Secretary of Agriculture showing that such drug has been tested and has not been found to be unsafe for use under such conditions." Dunn, 1027.

version been enacted, with this definition, devices would have had to be precleared.[80]

On April 14, 1938,[81] after an eight month delay, the revised version of S. 5 was introduced in the House with section 201 (g) and (h) defining "drug" and "device" respectively, and 201 (i) which defined "new drug" as:[82]

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Under this definition a "drug" is a "new drug" if it is not generally recognized as safe (or effective)[83] or one for which no new drug application is in effect. The exception for drugs recognized as safe and effective from this definition, eliminates the necessity of official evaluation of a product from which there is no reasonable possibility of danger.[84] Other drugs which do not fall within the exception must be precleared in accordance with Section 505.[85]

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[80] Section 8 . . . (c) The term "drug" means (1) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or any other animals; and (2) articles (other than food) intended to affect the structure or any function of the body of man or other animals.

[81] See footnote 80 at 774.

[82] See footnote 80 at 795.

[83] Drug Amendments of 1962, 76 Stat. 780.

[84] MR. COPELAND. (Statement re: S. 3073—75th Cong.) "The bill was introduced at the time when a large number of deaths occurred throughout the country from the sale of the elixir of which I have spoken. It developed that there was no means of protection, through the Public Health Service or the Bureau of Food and Drugs, to make certain that new preparations were given proper examination in order to insure that they were safe for human consumption. This is the purpose of the bill. Objections have been raised to it from various sources, but as objections have been withdrawn new ones have been made. It is the old history of any attempt to provide control in the matter of drugs." Dunn, 1021, see footnote 77.

[85] The definition of "new drug" is also amplified in the regulations: (2) (h) The newness of a drug may arise by reason (among other reasons) of: (1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstrum, excipient, carrier, coating, or other component. (2) The newness for drug use of a combination of two or more substances, none of which is a new drug. (3) The newness for drug use of the proportion of a substance in a combination even though such com-

(Continued on next page.)

The final draft of the bill was adopted in the House, June 1, 1938, and in the Senate, June 10, 1938. It was signed by the President, June 25, 1938.[86]

Subsequent History

Because of alleged dangers of new cosmetics, some legislators wished to increase the scope of preclearance to cosmetics and other products. In 1951 and 1952 a special committee investigated the use of chemicals in cosmetics.[87] After the hearings, the Committee issued a report. The report noted the injuries from deodorants, hair straighteners, and depilatories which could be prevented only after people were injured.[88] Among other examples, hair lacquers, fingernail lacquers, nail polish, lipstick, wave lotions and shampoos which also caused serious injuries.[89] The report concluded that the public could be safeguarded against like injuries in the future by "pretesting requirements, similar to that presently existing with respect to new drugs."[90]

In 1953, a bill, H. R. 2244, 99th Cong. 2d Session was introduced requiring pretesting of new cosmetics. No action was taken on it. In subsequent years, bills requiring pretesting of new cosmetics and devices have been introduced but none have been passed.[91]

[To Be Continued in the June Issue]

(Footnote 85 continued.)
bination containing such substance in other proportion is not a new drug. (4) The newness of use of such drug in diagnosing, curing, mitigating, treating or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body. (5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug. 21 C. F. R. § 130.1 (L)(1964).

[86] Dunn, 1015.

[87] H. Rep. 449, 82nd Cong., 1st Sess., at 3 (1951).

[88] H. Rep. 2182, 82nd Cong. 2d Sess., at 3 (1952).

[89] See footnote 88 at pp. 4, 5.

[90] See footnote 88 at 10.

[91] See, for example, 84th Congress: H. R. 4476 (101 Cong. Rec. 2255); H. R. 5036 (101 Cong. Rec. 3113); H. R. 5094 (101 Cong. Rec. 3301); 85th Congress: H. R. 4015 (103 Cong. Rec. 1224); H. R. 9153 (103 Cong. Rec. 13805); H. R. 4431 (103 Cong. Rec. 1574); 86th Congress: H. R. 1360 (105 Cong. Rec. 4181); 87th Congress: H. R. 1235 (107 Cong. Rec. 61); H. R. 11582 (108 Cong. Rec. 7753); 88th Congress: H. R. 6788 (109 Cong. Rec. 10175); H. R. 1235 (109 Cong. Rec. 56); H. R. 5777 (109 Cong. Rec. 6865); H. R. 8418 (109 Cong. Rec. 16932); S. 2580 (110 Cong. Rec. 4049); 89th Congress: H. R. 1235 (111 Cong. Rec. 89); S. 2350 (111 Cong. Rec. 19066); 90th Congress: H. R. 1235 (113 Cong. Rec. H. 174); H. R. 4486 (113 Cong. Rec. 911); H. R. 10726 (113 Cong. Rec.).

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

By FRANKLIN M. DEPEW

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

THE SIXTH SESSION of the Food and Agriculture Organization (FAO)/World Health Organization (WHO) Codex Alimentarius Commission was held at the Palais des Nations, Geneva, Switzerland, March 4-14, 1969. The session was attended by about 200 registrants made up of delegates and observers from about 47 countries—25 from the European region, 2 from North America, 10 from Latin America, 5 from Africa, 2 from the South West Pacific and 3 from Asia—and from 25 international organizations, as well as other interested observers. The total Commission membership at the time of the opening of the meeting was 63 countries and at the close 65 countries—25 in the European region, 2 in North America, 11 in Latin America, 14 in Africa, 2 in the South West Pacific and 11 in Asia. This is a substantial increase since the close of the Fifth Session when the total membership was 52.

The Session was opened in behalf of the Directors-General of FAO and WHO by Dr. P. Dorolle, Deputy Director-General of WHO. In his welcoming remarks Dr. Dorolle underlined the importance WHO attached to the work of the Commission and expressed his pleasure and that of the Directors-General at the increase in the membership of the Commission.

Composition of Sixth Session

The United States Delegation consisted of 14 representatives, including Mr. George R. Grange, Deputy Administrator, Consumer

Marketing Service, U. S. Department of Agriculture, its Chairman, and Mr. J. Kenneth Kirk, Associate Commissioner for Compliance, Food and Drug Administration, Consumer Protection and Environmental Health Service, Department of Health, Education and Welfare, his alternate, who were assisted by Mr. J. W. Slavin of the U. S. Bureau of Commercial Fisheries, and by the following industry representatives: Irvin A. Hoff, U. S. Cane Sugar Refiners Association, J. Russel Ives, American Meat Institute, Leonard K. Lobred, National Canners Association, Michael F. Markel, Esq., Jan J. Mertens, National Canners Association, Donald M. Mounce, Campbell Soup Company, Albert H. Nagel and Russel J. Olsen, both of General Foods Corporation, Robert G. Ruark, Corn Products Company, Dr. Howard C. Spencer, The Dow Chemical Company, and Dr. J. Bryan Stine, Kraft Foods Division of National Dairy Products Corporation.

During the session the Commission reelected Mr. J. H. V. Davies of the United Kingdom to serve from the end of this Sixth Session until the end of the Seventh Session. The Commission also reelected Mr. I. H. Smith of Australia. Mr. E. Mortensen of Denmark, and Professor Dr. Otto Högl of Switzerland as Vice Chairmen for the same period. The Commission also appointed Dr. B. Wilder of Austria as Coordinator for Europe to serve in that capacity until the end of the Ninth Session of the Commission.

Important Progress

The most valuable work accomplished by this session of the Commission was the approval at step 9 of the Codex procedure of commodity standards for honey, margarine, lard and rendered pork fat, edible soya bean oil, edible sesame seed oil, edible safflower seed oil, premier jus, edible tallow, edible fats and oils not covered by individual standards, canned Pacific salmon, white sugar, powdered (icing) sugar and soft sugars. The Commission also approved the General Standard for the Labeling of Prepackaged Foods and the Code of Hygienic Practice for Dried Fruits at step 9, also the tolerances in certain foods for hydrogen cyanide, inorganic bromide and malathion.

The other sugars, namely; glucose syrup, dried glycose syrup, dextrose monohydrate, dextrose anhydrose and lactose, had been approved at step 9 of the Fifth Session as had a number of standards for canned fruits and vegetables. However, the Secretariat delayed sending these out to governments. Just when these standards and

those approved at the Sixth Session will be sent to governments remains uncertain. The standards for fats and oils will be delayed for a while for reasons which will be discussed later. Approval at step 9 leaves only the acceptance of the standards by an appropriate number of governments to entitle the Commission to take the final step of publishing them as Codex standards.

Eight food colors found acceptable for use in food by the Codex Committee on Food Additives and which had been given acceptable daily intakes for man by the Joint FAO/WHO Expert Committee on Food Additives were approved by the Commission for the information of governments.

The Codex Committee on Food Additives decided at its March, 1968 Session that it would not propose a general definition for "food additives." As regards contaminants, the Committee agreed that these were substances whose presence in food were not intentional and therefore should be defined separately. The Commission at the Sixth Session also decided to defer further consideration of the definitions of "food additives," "contaminants" and "process" until its next session and to request further government comments on them. The United States delegation pointed out that the Committee on Food Additives at its next meeting will consider microbiological procedures and urged that experts familiar with microbiology attend the meeting.

Rules of Procedure

At the Fifth Session of the Commission, Canada proposed that regional standards be limited to "food produced exclusively and consumed mainly within the geographic region" on the ground that regional standards for commodities which move in world trade might operate to restrain trade. The Executive Committee, at its June 1968 meeting, recommended another solution to the problem of regional standards whereby the Commission would control their elaboration, namely, that such regions could only proceed with regional standards *if the Commission so determined.* After lengthy debate a vote was taken on the Executive Committee proposal. The vote showed 37 countries present with 22 for, 14 against and 1 abstention. As the Rules of Procedure require a two-thirds majority of the votes cast for an amendment or addition to the Rules, the proposal failed.

General Principles

Other items debated at length were proposed amendments to the General Principles of the Codex Alimentarius Commission as they relate to the Purpose of the Codex, specifically to provide for Codes of Practice, Guidelines and other recommended measures. The need to express the purpose of protecting the consumer was stressed and the delegate of the International Association of Consumers' Unions expressed her appreciation of this view. In the course of discussion it was pointed out that the Codex could only be expected in its early years to be a compendium of food legislation in the various countries which would make it easier to learn what the differences are in the laws of the various countries. It was stated that the Codex could not be expected to result in an immediate harmonization of food laws and standards but that it would lead little by little to ultimate harmonization of them.

The Commission approved the recommendation of the Committee on General Principles that the provision for "Acceptance with a Declaration of More Stringent or Supplementary Requirements" be abolished and approved the Committee's recommendation of a revised text for "Acceptance with Minor Deviations." This text provides for the inclusion of all types of deviation if these are judged to be minor by the Commission. The delegate of West Germany said the acceptance procedures raised a number of difficult questions as to their legal implications and as to the practicability of the procedures. He said further that they impose extensive obligations on accepting countries without the principle of reciprocity. He expressed concern that the present Rules would prevent many countries from giving full acceptance and proposed the establishment of a group of legal experts under the Codex Committee on General Principles to examine the various questions which he felt to be unresolved, it being understood that the proposal should not in any way delay the progress of the work on standards. Several delegations supported this view but the majority felt this unnecessary and that the acceptance procedures were provisional in nature and could be reexamined if necessary in the light of experience.

Food Labeling

The Commission considered the General Standard for the Labeling of Prepackaged Food and decided by a majority of the members present that it should be a general standard rather than a guideline. It was then advanced to step 9 but with major revisions. The Euro-

pean countries objected strenuously to the provision in the standard as approved by the Codex Committee on Food Labeling that all ingredients be declared on the label. It was proposed and adopted that, where national legislation does not require this, acceptance can be on the basis that the ingredient information provided on the label need only be sufficient to enable the consumer to understand the nature and worth of the food, provided that the food is of well known composition and the absence of a declaration of ingredients is not prejudicial to the consumer. Presumably, the accepting government is the body which can decide if these conditions are met. The delegate of the International Association of Consumers' Unions supported the need for a general standard for unstandardized foods and the showing of all ingredients. The United Kingdom pointed out that it is exactly in the field of unstandardized foods that the consumer needs the information required by the standard. The standard, as approved, includes a number of class names for substances which do not have to be declared by their common or usual names, such as herbs, spices, animal and vegetable fats and oils, colors, flavors, emulsifiers, bleaching and maturing agents, etc. The Commission said this list is not exhaustive and that it can be amended later by the addition of further class names. It was decided to defer until the next session consideration of the question of whether the Codex Committee on Food Labeling could consider advertisements in relation to claims in labeling.

It was decided that the next meeting of the Committee should be held in Rome immediately before the next session of the Commission rather than in Ottawa, the capital of the chairing country, Canada, if it is determined that a meeting is needed before the next Commission session.

Standards for Fats and Oils

There was substantial opposition to permission to use colors and emulsifiers in the General Standard for Edible Oils and Fats. Switzerland suggested a vote to eliminate their use in oils. It was pointed out by the United States that the Chairman should define the difference between fats and oils before a vote be taken on the matter. The Chairman said that, as the experts had been unable to do this in the Fats and Oils Committee, he could not do so and no vote was taken. France suggested that, as there was so much disagreement about the standard, it should be given a further chance to ripen by being

sent back to the Committee rather than being passed to step 9. Otherwise the standard might be accepted with many reservations which would be undesirable. The Chairman suggested that the Commission reflected the same division that had been expressed in the Committee and that there was remarkable unanimity except with respect to the additives. On a vote the Standard for Edible Oils and Fats was passed to step 9 with 11 countries for, 10 against and 15 abstentions (after marine oils had been excluded).

It was then agreed with respect to the additives proposed for use in fats and oils that the Joint FAO/WHO Expert Committee on Food Additives will be requested to consider at its next session those additives in the standard which have not yet been evaluated toxicologically. The Codex Committee on Food Additives will then be requested to consider at its next session the endorsement of those food additives in the standard which it has not yet endorsed, and for which the Expert Committee was able to establish an acceptable daily intake (ADI) or temporary ADI. When sent to governments, the standards will contain only those additives which have been previously endorsed, or temporarily endorsed, and those which may be endorsed or temporarily endorsed at the next session of the Codex Committee on Food Additives. Any additives not so accepted will be deleted from the standard at that time. However, the possibility was left over of reconsidering them at the next session of the Fats and Oils Committee and to again refer them to the Additives Committee for ultimate inclusion in the standards. It is thus essential for American industry to work closely with these Committees to assure the approval of any additives felt to be needed.

With respect to margarine, at the suggestion of the United Kingdom, it was decided to add the following additional requirement: Maximum water content – 16% of the product, by weight.

Standard for Honey

Further evidence of the difficulties in securing worldwide harmonization may be found in the actions taken with respect to the standard for honey. Canada proposed that reconsideration be given to the decision taken last year that this standard be a regional one. This proposal was defeated by 15 votes to 9 with 11 abstentions. The United States objected to the values established for diastase activity and hydroxymethylfurfural content, on the ground that much of the honey produced and consumed in the U. S. would not meet those

values. These provisions of the honey standard are not in conformity with the Codex principle of establishing minimum standards for wholesome acceptable products. The honey standard contains criteria for a special quality product which excludes much good and wholesome honey.

Standard for Sugars

In the discussion relative to the standards for white sugar, powdered (icing) sugar and soft sugars, the question was raised by several delegations as to whether sulphur dioxide which is used during the processing of sugar, essentially as a bleaching agent but not added to the end product, should be considered as a contaminant or a food additive. It was decided that it should be considered a food additive but the labeling provisions were amended to delete the requirement that it be shown on the label. This decision was also made applicable to the sugars passed to step 9 at the Fifth Session, and was strongly supported by the European countries. It seems inconsistent with their general attitude of opposition to the use of food additives and their insistence that any used should be declared on the label.

Food Standards Work in Africa, Asia and Latin America

At the Fifth Session of the Commission, the Secretariat was requested to prepare surveys on the needs of Asian and Latin American countries in respect of the patterns of trade in foods and in respect of food legislation and standards. These reports were prepared and submitted to the Commission. Some delegations were of the opinion that the information contained in these papers stressed the need to consider the pattern of trade between countries before embarking on new work. A delegate from a Latin American nation stated that there was need for increased collaboration between the JOINT FAO/WHO Codex Alimentarius Commission and the Pan American Standards Commission which is recommending food standards for adoption by the countries of South and Central America and that greater publicity should be given to the work of the Codex Commission in the region of Latin America. The United States' delegate advised that the United States of America Standards Institute had informed the Pan American Standards Commission that food standards work in Latin America should be coordinated with the Codex Commission. It was agreed that these papers and the

paper on Africa prepared for the Fifth Session should be sent to the countries of the regions concerned requesting further information so that more complete and up-to-date reports could be put before the next session of the Commission. Ghana suggested that the time was now opportune to set up a Coordinating Committee for Africa. The Commission considered that it would be premature to embark on the establishment of this committee before the membership in the Commission of the African countries had increased.

Progress on Other Standards

Also sent out for comments at step 6, that is for a second round of comments, were the commodity standards for edible fungi, natural mineral water, olive oil, mustard seed oil, various fruit juices, canned green peas, canned mushrooms, canned strawberries, canned plums, canned raspberries, canned fruit cocktail, frozen gutted Pacific salmon, frozen fillets of cod and haddock, and canned shrimps and prawn. The Commission further sent out at step 6 the Sampling Plans for Prepackaged Foods, Technical Procedures for Sampling Foods and the Codes of Hygienic Practice for Desiccated Coconut, Dehydrated Fruits and Vegetables including Edible Fungi, and Quick Frozen Fruit and Vegetable Products. In addition, the Commission adopted tolerances, temporary tolerances and practical residue limits for aldrin, dieldrin, diphenyl, heptachlor and heptachlorepoxide, hydrogen phosphide, lindane, maliathon, inorganic bromide, piperonyl butoxide and pyrethrins, and passed them to step 6.

The Commission approved Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses. These included the provision that foods for special dietary uses should be freely available wherever foods are sold and without licensing requirements not imposed on foods generally.

Other Matters Considered

Dr. H. Steiger, Chief of Division of the European Economic Community (EEC), reported that pursuant to the treaty of Rome which established the EEC, free trade was required to occur in the countries which were parties thereto by January, 1970. He expressed the hope that many food law problems would be resolved prior to that date. He submitted a written report on progress toward har-

monization which showed that general regulations covering packaging material, dietetic foods, labeling, preserves and canned food, and sampling procedures were in the course of preparation. It also summarized the state of the work on food additives and on commodities or commodity groups. Mr. Steiger said he was not in a position to give a clear indication of when the regulations referred to in the report would come into effect in view of the fact that this subject was presently under discussion within the Community.

The Council of Europe reported it is working in the field of migration of chemicals from packaging materials and also in the field of flavorings and will submit its recommendations to the Commission in due course.

The Commission postponed any action on standards for soups, broths and edible ices, with respect of soups and broths until receipt of answers from governments to a questionnaire relative to need and national legislation, etc., and with respect to edible ices until a report to be prepared by the Secretariat covering international trade was submitted.

The foregoing report discloses that while progress towards harmonization of food laws may be expected to proceed, it will be at a slow pace. There are many difficulties yet to be overcome. However, much solid progress was made at this Sixth Session. Messrs. Grange and Kirk and all other members of the United States Delegation worked most diligently and effectively to protect the interests of the American consumer and the American food industry.

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

U. S. FAO Inter-Agency Sub-Committee on Codex Alimentarius
Agriculture Marketing Service, U. S. Dept. of Agriculture
Washington, D. C. 20250

[The End]

Food Control and Food Standards for Consumer Protection in Developing Countries

By HANS P. MOLLENHAUER

Hans P. Mollenhauer, Oberregierungsrat in the Federal Ministry of Health, Was the Alternate on the Delegation of the Federal Republic of Germany to the Second and Third Meetings of the Codex Alimentarius Commission. He Is Now With the Food and Agriculture Organization (FAO) of the United Nations, as Chief of the Food Standards, Additives and Regulations Section.

FOOD CONTROL in its various aspects is as old as human civilization if we understand it to be a form of supervision exercised by some authority over production and supply of foods in groups of human population.

The reasons behind food control have been as varied as the history of human relations in civilized life. Two broad political motives may be recognized among these: one is the control of available food in order to rule the population. Whoever is in possession of the food supplies is in a position to yield power. In this sense, authorities may be interested in accumulating foods in preparation for war or taking charge of food stores and distributing rations during war times. The other motive for food control is the wellbeing of the population without any ulterior reason. In the former case the authorities take possession of the food supplies in various ways, in the latter they supervise the exchange of foods between producer, distributor and consumer, and it is this latter situation which will be the subject of my further deliberations.

History of Food Control

In antiquity, we find a well-organized system of food control which, at least in Rome, was based on both motives of state control

over available supplies in order to exert political power such as distribution of funds to certain classes for gaining their favor and votes, as well as for protecting the consumer against poor quality, fraud and high prices (the Lex Julia de Anona).

After the disintegration of the Roman Empire, which for a certain period was survived by its organization of food control (the office of Praefector Anonae existed well into the seventh century), the food control was as disorganized as the political scene.

In the early Middle Ages, a certain amount of food control was maintained by local authorities and principalities with respect to the quality of foods, for instance, those which were to be delivered to the troops and feudal institutions. There was also some control of the goods being delivered to public markets. An interesting development of consumer protection is noticeable with the strengthening of the guilds. The guilds exercised a very strict control of quality and price including raw materials, methods of processing and quality, and weight and measure of the final product. This was a sound reaction to the general political disorder: the industry protected itself by maintenance of a certain quality standard enforced by measures of self-control. It was in those days that the famous Nuremburg gingerbread makers, the English cloth makers, the Bavarian beer brewers began to build up their image of high quality which has stood them in good stead ever since.

With the disappearance of the guilds, food control was again left to local authorities until about the middle of the nineteenth century. The newly-rising national governments recognized the need for a well-organized system of food control. The lead in Europe was taken by the British with their establishment of the Pure Food Act in 1860. That Act was followed by the German food laws in 1886. These laws were the beginning of the modern era of consumer protection against fraud, misleading practices and the marketing of food that is harmful to health.

In concluding this section on historical background, the somewhat varied development of countries which were subject to occupation by other countries may be mentioned. In some cases the occupying forces interfered with the local food supply in a form of food control. This could mean that a country was forced to change its economic system in order to produce certain commodities for export. This was sometimes to the advantage of the occupied coun-

try, as in the case of the Romans introducing viticulture on the Moselle in Germany. Other examples in more modern times would be monocultures replacing a mixed agricultural economy. The economical and commercial effects of this latter occurrence in Ceylon have been illustrated by V. Nadarajah.[1] The effects of changing a traditionally agricultural economy into an industrialized one may influence the social pattern to such an extent that the country becomes dependent on foreign markets for most of its food supplies. The effect in Ceylon had been that low quality foods which were often unsound found their way onto the market. Some of these goods were imported from countries which refused cargoes of foods that fell below the requirements of their own food standards. This, of course, is a common occurrence—not limited to Ceylon—that foods which are below the standards of one country are shipped "elsewhere."

The Present Situation

It is a common problem that the quality level laid down by local standards and regulations varies from country to country, putting the consumer of a country with a low standard level or with the absence of any such standards at a disadvantage.

The need for consumer protection in the developing countries and particularly in those which have only recently gained their independence differs to a certain degree from more industrialized countries where there has already been some quality control and health protection in the field of foods and whose governments are now striving to harmonize their varying regulations internationally.

In developing less industrialized countries, there are needs for consumer protection very similar to those in other countries, but some problems are specific and need particular attention. In some countries, there are remnants left from the times of government dependence during which the laws of the ruling country had been introduced—laws which had been developed under different circumstances and from different economic backgrounds. A bad example would be an ordinance for bread, prohibiting the use of any other flour but wheat flour in a country where there is no wheat available. Some countries may be entirely dependent on imported food supplies; in this case one could afford high quality standards similar to those of the countries of origin. Some countries may, however,

[1] Contribution to FAO Regional Food Legislation Seminar, Bangkok, 1962, "Food Standards and Legislation in Ceylon."

go through a temporary phase of developing their own resources as against imported foods. Here the question arises whether the imported foods should be allowed to be of a standard lower than international standards if, at least temporarily, lower standards are needed for locally produced foods. This can, of course, only concern quality and not health.

Many developing countries do have a food law—either inherited or recently elaborated—but lack the facilities for implementation. This may be one of the most marked differences compared with more industrialized countries. They do not have enough trained staff to work as food control officials at various levels, starting with the inspector or controller-policeman, who draws the samples, right through to the laboratory chemist and magistrate, who finally deal with the results of these efforts.

A further field that needs improvement in developing countries—possibly more than in others—is the elaboration of individual commodity standards to fill in the broad areas circumscribed by the basic food law, that is, to provide detailed answers to the questions when a particular food is adulterated or misrepresented. This is particularly so with traditional foods.

Most countries, irrespective of their state of industrialization or development in the normal sense, need further development in the field of consumer education. The educated and informed consumer is an important partner in the economy of all countries.

Methods of Food Control for Consumer Protection

Food control is carried out best at three levels:

I. The Law
- (a) Regulations
- (b) Commodity Standards
- (c) Codes of Practice for Hygiene, Processing, etc.

II. Food Inspection
- (a) In-plant quality control
- (b) Official inspection and control for consumer protection
  - (i) taking of samples
  - (ii) analysis
  - (iii) prosecution

III. Consumer Education
- (a) Meaning of food standards
- (b) Quality and value consciousness
- (c) Establishment of consumer representation

I. *The Law.*—The whole edifice of food control is based on a general law which states what authorities are responsible for its administration and execution and which lays down certain principles, such as the definitions of food, appliance, food additive, contaminant and residue; it will also contain basic principles concerning health, adulteration, misrepresentation or fraudulent practices. The commodity standards state what the designation, composition and appropriate labelling of a particular food item or group of foods should be. From this information, the magistrate or judge may rule whether food is adulterated, etc. Further useful legal instruments for encouraging fair practice in manufacture, processing, handling and storage of food are official manuals or codes of practice, less formal than laws or regulations themselves; these are very useful because they sometimes refer to acts or circumstances which cannot be fully examined by later analysis. The Legal Department of the Food and Agriculture Organization (FAO) has published a general guideline[2] for the elaboration of such basic laws.

II. *Food Inspection.*—The examination of the composition, quality and quantity of a food is carried out at two levels. The first is in-plant control carried out by the manufacturer for various reasons. He has an interest in the proper functioning of his manufacturing process and is desirous of consistently producing products of a similar "standard." This "factory-standard" does not necessarily agree with the official food standards. Some manufacturers will strive to produce an average slightly above the official standard, some will produce an average to agree with the official standard. The unfair practice of continuously producing an average slightly below the official standard need not be mentioned here. For newly-established industries trying to gain a new market, it would be a good policy to aim at producing an average that lies above the legal minimum requirement in order to allow for technical difficulties that may exist.

Whatever the policy, the employment of a quality control staff in the factory is of paramount importance for the wellbeing, not only of the consumer but also of the economic situation of the manufacturer. Proper management and costing of any manufacturing process are inseparably linked with quality control.

During its manufacture and especially after having been offered for sale, the food product is subject to official control. The purpose of this control is exclusively consumer protection. Samples are col-

[2] "Food Legislation: Basic Principles" (Note by the Legislation Branch of FAO) PG/67/5—SP10/30—WS/63509.

lected at random, analyzed and evaluated by appropriately trained personnel. It cannot be over-emphasized that any legal provision is quite ineffective if not followed up by efficient enforcement. The staff can be classified into two groups. One is the inspector who physically inspects the food manufacturing and processing plants, cold storage, markets and other points of storage, distribution and sale. He is familiar with the current provisions and requirements of food standards, codes of hygiene, etc. and has certain authority which is similar to that vested in the police force, to enter premises and take samples under specified conditions.

At this level, most countries suffer from a deplorable lack of properly trained personnel. The inspectors mostly belong to various authorities—federal, state, municipal or others; they are sometimes members of the police force with little specific training in food technology and legislation, which is a prerequisite for efficient execution of their duties. The next category of food control officials consists of chemists, veterinarians and physicians who analyze and evaluate the sample. This is done in special laboratories established and officially authorized for this purpose. They should not normally engage in any commercial activity such as giving expert opinion and expertise to the industry for payment.

A further consideration in this chain of food control is the availability of magistrates and courts of justice who can deal with matters concerning the food law within a reasonable time. In many cases legal procedure requires the storage of samples until the case comes up in court, and this may take longer than the normal shelf life of the food item.

III. *Consumer Education.*—In these modern times we have gone a long way since man learned to build motor cars, to construct comfortable houses and to produce patent convenience foods. For driving a motor car, we need a license; for building a house an architect and a lawyer, but for spending about one-third of our income on food, we rely on very little training.

Until three generations ago we needed little training to evaluate the quality of food because most people were still very closely related to the production and processing of food, and they could rely on their ability to judge its quality and monetary value. This has changed to a considerable extent, since the larger number of people now live in cities removed from the production areas. All they see now is food carefully and hygienically wrapped and sealed so that

they cannot touch, taste or smell it for quality. Quality in this context is the sum of aesthetic and nutritional value and suitability for a desired purpose (convenience).[3] In some cases even the quantity is hard to evaluate, and comparison of the price of various sized packages is only possible with great difficulty. What is needed is a basic training in the evaluation of foods and in the understanding of modern food processing.

In the past in some countries, there have been heated debates because of this lack of understanding between the factions of "consumers" and "industry." An understanding of the needs of modern technology can only be reached with a joint effort by government, science, industry and "consumers."

Some countries already provide for the participation of some consumers' representatives in the elaboration of food laws and standards given. However, in many cases the consumers' representatives are sufficiently equipped neither with knowledge of food technology and the technical experience of law-making, nor with sufficient money and staff. In order to play their role efficiently, consumers and their representatives, need as much training as the food control official or the industrial quality control employee. An important subject for training is that of food standards; for anybody engaged in elaboration of food standards, it is quite surprising to find how little knowledge the average consumer has of these things. Controversies between industry and the authorities over certain details of food standards mean very little to the average consumer for lack of knowledge. It would be quite a shock to many of them to learn that milk, for instance, contains about 85% water, or chocolate up to 50% fat. This widespread lack of detailed knowledge can lead to two conclusions: either that the efforts of authorities concerned with the quality of foods (except the health aspect) are uncalled for because the consumer does not know any better, or that the consumer must be educated and informed to a much greater extent than he has been in the past. The problem of the lack of consumer education and quality consciousness is not limited to countries of any particular level of industrialization or development. However, in less industrialized countries where consumer education has not received much attention so far, governments have a unique opportunity of taking the lead in initiating consumer education programs as against other

[3] "Food Processing and Household" published by German Society for Home Economics, Stuttgart, 1968 (in German).

countries where such programs and organizations have sprung up in a more haphazard way.

Future Work

There can be no single line of attack for intensifying consumer protection and education, nor is there a clear distinction possible between more and less developed countries. Regarding the *basic food law,* most countries already have some legal instrument which may be new or may stem from older times, according to their general legal concept. As previously mentioned, a general guideline for the requirements of the basic food law has been elaborated by FAO and can be consulted by the legal authorities in every country. Further advice may be useful from experts, however, and this should be dealt with by the legal departments in each country according to their acquired system.

The situation is quite different in the technical field, for example, food standards, where mostly technological and economical rather than legal knowledge is required. Many countries have already elaborated their own standards and are now engaged in trying to harmonize their standards internationally through the Codex Alimentarius Commission, which need not be described here.

In this respect, developing countries (that is, countries, including some industrially well-developed countries), which are about to develop their food standards are in a favorable position in that they may avoid the mistakes which have been made in the past. For such countries, participation in the work of the Codex Alimentarius Commission and its technical committees would be very beneficial indeed.

Less industrialized countries may have some difficulties in fully participating immediately because of a lack of travelling funds, or of appropriate staff, or simply because the Codex Standards would not be of much use in the present state of their economy.

An important provision of the Statutes of the Codex Alimentarius Commission could be of particular interest to developing countries, and that is the provision for making either regional or world-wide standards. The Rules of Procedure explain in detail how a Regional Committee may be established and how it functions. The formation of such Regional Committees could be instrumental in propagating the idea of international food standards work in various regions of the globe. It might be easier for the countries within a region to first meet with their neighboring countries who are willing to work on international food standards. Besides such psychological

and political advantages, regional committees would, of course, have the urgent task of elaborating standards for traditional foods which are produced and traded inside the region.

Much future work is needed in the field of food inspection. Many countries which already have a satisfactory law are suffering from inadequate means of inspection, and this is a question of availability of personnel and their training. This holds likewise for industrial quality control as well as for supervision. Projects for agricultural and industrial development financed by the United Nations Development Program or any other international or national agency, should therefore include provisions for the training of quality control experts and inspectors. They should preferably be trained together. Similarly, the training of food chemists and veterinarians should be envisaged concurrently with the establishment of appropriate laboratories. The training of inspectors and chemists could initially be carried out abroad in countries where a fully established food control service exists, prior to the establishment of local centers for training of food inspectors.

In the field of consumer education, programs should be developed for increasing quality-consciousness and popularizing the introduction of food standards. Governments could establish sections in an appropriate ministry to deal with consumer questions and with consumer training programs. The United States Government, for instance, issues regular publications explaining to the consumer the methods of food control and inspection and describing various provisions of food standards in a language understandable to a layman.

Where a consumer organization does not exist, one could be established which would extend and enlarge these activities. A prime condition for the effective functioning of such consumer organizations is the proper training of their officials and representatives similar to and preferably together with industrial quality control staff and food control officials. It would be worthwhile for the industry to invite suitable people from consumer organizations to be trained in quality control and assessment.

The final aim of any such efforts by government, industry and private organizations should be the making of a well-informed consumer, capable not only of enjoying his food but also of playing the important role which is expected of him as a consumer in a modern economy: the furtherance of a healthy agricultural economy and a processing industry capable of supporting a modern standard of living.

[The End]

ANTIBIOTIC SENSITIVITY DISCS ARE DRUGS, U. S. SUPREME COURT SAYS

The Supreme Court has ruled that antibiotic sensitivity discs are drugs within the meaning of the Federal Food, Drug and Cosmetic Act (FDA). As a result of the ruling, the Food and Drug Administration's authority to issue its 1960 regulations was sustained. The regulations require the testing and certifying of the antibiotic sensitivity drug. Consequently, such products must be approved by the FDA before they are marketed.

The discs are used to test the sensitivity or reaction of a specimen taken from a patient to the antibacterial or antiviral units contained on the disc. The purpose of the test is to furnish doctors with the information that will aid them in treating diseases previously diagnosed.

In reversing the Court of Appeals for the Sixth Circuit, the Court said that Congress did not intend to limit the definition of a "drug" to the medical concept of articles that are administered to man, either internally or externally. Congress intended a literal reading of the definition of a "drug" as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.

The legislative history and purpose of the Food, Drug and Cosmetic Act also precluded classifying the discs as devices. Devices are not subject to pre-market clearance under the provisions of the Act. The Act is a form of remedial legislation which must be given a liberal construction to protect the public health, the Court said.

U. S. v. An Article of Drug, CCH FOOD DRUG AND COSMETIC LAW REPORTS ¶ 80,231, U. S. Sup. Ct., April 28, 1969.

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