Diet Therapy

The Role of the Food and Drug Administration in Nutrition

GEORGE P. LARRICK, D.SC.*

EVERY physician, dietitian and nurse, indeed, everyone concerned with nutrition, should know what the Food and Drug Administration does in nutrition and related areas of interest to the consumer. Standards for "enriched" foods, nutritional "quackery," safety of food additives, "tolerances" for pesticide residues on food crops—these are phrases which only comparatively recently have come into our vocabulary. Such phrases are loaded with implications for the safety, wholesomeness, nutritional quality and integrity of foods for both general and special dietary use. They are, of course, of special interest to nutritionists. This is not only a matter of professional competence, but also involves an obligation to know the strengths and weaknesses of our protective laws, and to be alert to both necessary and undesirable changes which may be proposed.

As an introduction to the work of the FDA in this area, let us look briefly at the broad pattern set forth in the Federal Food, Drug, and Cosmetic Act of 1938.

THE BREADTH OF CONSUMER PROTECTION

This law is a revised and greatly strengthened version of the original Federal Food and Drugs Act of 1906. Dr. Harvey W. Wiley, Chief Chemist of the U. S. Department of Agriculture at the turn of the century, deserves a generous share of gratitude for his crusade on behalf of the original act. The major objectives of the current law are sometimes summarized as:

Safe, effective drugs and cosmetics.
Pure, wholesome foods.
Honest labeling and packaging.

The law forbids shipment in interstate commerce of "adulterated" or "misbranded" foods, and defines adulteration and misbranding to accomplish its purpose of protecting consumers. Violators may be fined or imprisoned, or both, and illegal goods may be seized to remove them from the market. All actions must be taken through Federal district courts. The court may also issue an "injunction" to prevent repetitious violations or any violation which appears imminent.

IMPORTANT DEFINITIONS OF ADULTERATION AND MISBRANDING

A frequent concept of the meaning of "adulteration" is simply the addition of a substance to cheapen the article. While the law includes this concept in its definition, it goes much beyond this. Some of the important definitions of *adulteration of food* contained in the law are these:

Preparation, handling or storage under unsanitary conditions.

Presence of filthy, putrid or decomposed material.

From the Food and Drug Administration, U. S. Department of Health, Education, and Welfare, Washington, D. C.

* Commissioner of Food and Drugs.

Presence of any substance which would make the food injurious to health.

Presence of any residue from pesticide or food additive not generally recognized as safe, except as may be permitted by specific regulation setting a limit (tolerance) on the amount which may be present.

Presence of any coal-tar color not listed by the FDA as harmless and tested for purity in laboratories of the FDA.

Omission of an important ingredient, or substitution of a cheaper ingredient, or use of an ingredient to make the food appear better than it is.

Some of the important definitions of *misbranding of food* are:

False or misleading statements on the label or in labeling.

Deceptive packaging or shortage in net contents.

Failure to label the food as an imitation, if it is an imitation of another food.

Omission of special dietary information needed by users (as, for example, the sodium content of foods sold for use in low-sodium diets).

Failure to conform to any standard of identity (composition), quality or fill of container set by regulation.

Omission of the information required by law to be on the label: the common or usual name of the food and of each ingredient, with certain exceptions; the name and address of the manufacturer, packer or distributor; an accurate statement of contents; and declaration of the presence of any artificial flavor, artificial color or chemical preservative.

The law, of course, contains other definitions of adulteration of food and misbranding, but they all add up to require that a food be safe, clean, wholesome *and what it purports to be, both in quality and quantity*. There are also, of course, special definitions for adulteration and misbranding of drugs and cosmetics.

PREMARKETING CONTROL FOR SPECIAL PRODUCTS

Most consumers, and perhaps many doctors and nutritionists, do not understand that special *premarketing* controls are provided for a few special classes of products only; and that for the great bulk of foods, drugs and cosmetics the law operates through periodic inspection of factories and sampling of products after they are on the market.

The following is a list of products for which there is premarketing control, and the type of control provided for each:

New drugs: manufacturers must submit experimental proof of safety under conditions of proposed use.

Antibiotics (penicillin, streptomycin, chlortetracycline, chloramphenicol and bacitracin and their derivatives, only) and insulin: manufacturers must submit proof of both safety and efficacy; and each batch must be tested in FDA laboratories for purity and potency before it may be distributed.

Pesticides: manufacturers must submit experimental proof of the amount of residue that will remain on crops if directions on the label are followed; and that this amount of residue will not be harmful. The FDA then sets a safe "tolerance" for each crop, and this amount of residue must not be exceeded on the food as shipped.

Food additives: manufacturers must submit proof of safety of the amount to be used, and of technical effect or benefit; the FDA sets safe tolerances for use in specific foods, and specifies any other conditions of use necessary to protect the health of the public.

Coal-tar colors: the color must be one listed by the FDA as "harmless and suitable for use;" and each batch must be tested for purity in FDA laboratories. (With one exception covered by special legislation, the law does not permit the FDA to limit the amount of a listed coal-tar color. Some colors originally believed harmless have recently had to be removed from the list of permitted colors, because new tests have shown that large amounts will cause injury to animals. An amendment to the law is being sought to permit the FDA to set safe limits on the amount of a color which may be used.)

For products in these classes, marketing without advance clearance by the FDA, or except in compliance with the terms of that clearance, is *per se* a violation of the law.

To review the manufacturers' experimental evidence of safety of new drugs, food additives,

TABLE I

Minimum Daily Requirements of Vitamins Established for Labeling Purposes

Age Group	Vitamin A (USP Units)	Vitamin D (USP Units)	Vitamin C (USP Units)	Thiamine (mg.)	Riboflavin (mg.)	Niacin (mg.)
Adults	4,000	400	30	1.0	1.2	10
Children (all ages)	3,000	400	20	...	0.9	...
6 yr. or older	...	...	..	0.75	...	7.5
Less than 6 yr.	...	...	..	0.5	...	5
Infants	1,500	400	10	0.25	0.6	...

and pesticides, the FDA has a headquarters staff composed of some of the country's leading scientists, including physicians, pharmacologists, chemists, nutritionists, bacteriologists and workers in related fields. These scientists not only must pass judgment on the adequacy of the work done by the manufacturers, but also must conduct or direct their own studies where necessary to check on doubtful points. On their advice the Commissioner of Food and Drugs determines whether or not these products may be marketed.

These scientists also develop highly specialized laboratory procedures needed by the field laboratories of the FDA to detect and prove violations of the law; they also make certain types of assays—for example, of certain vitamin products and bioassy drugs—which cannot be conducted in the field laboratories. The FDA's Division of Nutrition also conducts certain special investigations which will be of interest to the reader, and which will be mentioned later.

ALL OTHER PRODUCTS POLICED BY FACTORY INSPECTION AND MARKET SAMPLING

For all products other than those listed above, the policing of purity and safety begins with scientifically trained inspectors and scientists in seventeen field laboratories in major cities throughout the country.

The 430 Food and Drug Inspectors of the FDA are not only experts in the location of any defects in a food, drug or cosmetic factory operation which may result in an inadvertent violation of the law but also in the detective work necessary to catch the occasional deliberate violator. Sanitation in plants, manufacturing processes, suitability of raw materials, labeling and packaging practices and control in plants to guard against mistakes—all are subject to the inspector's strictest scrutiny. Refusal of a manufacturer to permit inspection is a violation of the law.

Most manufacturers value highly the inspector's comments on their operations to help them keep out of trouble; but, of course, if a violation is found, the inspector's report sets in motion a series of actions which may end up in the Federal court.

Backing up the inspectors are trained chemists and other scientists in the seventeen FDA District Laboratories, who examine samples from interstate shipments to detect any violation of the law. These scientists may develop evidence to support what the inspector has observed, or they may find evidence of a violation which was concealed from the inspector, which could not be detected except by laboratory analysis.

Inspectors of the FDA can examine the nearly 90,000 food, drug and cosmetic establishments subject to the Federal law on an average of about once every three to four years. A Citizens Advisory Committee which studied the Food and Drug Administration in 1955 believed the long interval between inspections to represent a serious defect in consumer protection. A three to fourfold expansion of the 1955 staff of approximately 250 inspectors was recommended, and considerable progress has been made toward this goal. The increase of $2,883,000 in our appropriation for 1960 will enable us to catch up with the minimum rate of progress recommended by the Committee, which called for completion of the growth within a five-to ten-year period.

TABLE II
Minimum Daily Requirements of Minerals Established for Labeling Purposes

Age Group	Calcium (mg.)	Phosphorus (mg.)	Iron (mg.)	Iodine (mg.)
Adults	750	750	10	0.1
For pregnancy and lactation	1,500	1,500	15	...
Children (all ages)	750	750	...	0.1
6 yr. or older	...	...	10	...
Less than 6 yr.	...	...	7.5	...

FDA PROGRAMS OF SPECIAL INTEREST TO NUTRITIONISTS

Vitamin- Mineral Products

The law requires informative labeling on foods purporting to have value for special dietary uses. For example, foods claiming to be of special value as dietary supplements because of their vitamin or mineral content must specify the amount of each vitamin or mineral on which such value is based, in terms of the proportion of the minimum daily requirement supplied by a quantity of the food which might reasonably be eaten in a day.

For this purpose minumum daily requirements for six vitamins and four minerals are designated by regulation. Tables I and II list these values.

The requirements shown are amounts of the vitamins and minerals that are adequate to prevent deficiency and to allow for normal physiologic functions of the human body. These values were established in a wide variety of experimental and clinical studies. The same body of scientific information was the basis for the Recommended Dietary Allowances published by the Food and Nutrition Board of the National Research Council which are somewhat greater than the minimum daily requirements. The most recent National Research Council bulletin (Publication 589, 1958) entitled "Recommended Dietary Allowances" explains that the allowances for vitamins and minerals cited are liberal since they are meant to afford a margin of sufficiency above minimum requirements, are widely used in the planning of diets, and are designed to maintain good nutrition in all healthy persons under all variations in the population at large.

The differences between the two sets of values are not great, except for ascorbic acid, where the Recommended Daily Allowance is two and a half times the Minimum Daily Requirement. It must be recognized, however, that frequent reference to both "M.D.R." and "R.D.A." in the labeling of vitamin-mineral products presents a likelihood of consumer confusion, and suggests the desirability of a single set of authoritative values.

Other Foods for Special Dietary Uses

An artificial sweetener, or a food in which it is used in place of sugar, must state on its label that it is for use only by persons who must restrict their intake of ordinary sweets. A so-called "low-calorie" food must state the number of calories in a specified quantity, and if the calorie content is not significantly lower than that of other foods, "low-calorie" claims are considered false and misleading.

Foods purporting to be of value for low-sodium diets must state the number of milligrams of sodium per 100 grams of food, and per average serving.

The FDA examines samples of dietary supplements and other foods for special dietary uses to check the accuracy of the composition declared on the label, and to see that no false or misleading claims are made.

Food Standardization and Enrichment

The FDA is authorized to issue regulations setting standards of identity, quality and fill of container for processed foods. Industry, consumers, dietitians and nutritionists, and other interested persons may participate in the standards-making process. Consumers, dietitians and nutritionists, for example, might contribute information as to what consumers expect the food to contain. A standard must promote honesty and fair dealing in the interest of consumers.

A public hearing is held on any controversy as to what the standard should be. The standard as finally issued must be based on the record of the hearing, or on the facts of record submitted by interested parties.

For example, some of the standards issued to date:

Set minimum fat and maximum moisture for many cheese and cheese products and for oleomargarine.

Set minimum oil content for salad dressings.

Set minimum tomato solids content for tomato ketchup, tomato juice and tomato paste.

Set minimum fruit content for many jams, jellies and preserves.

Specify permissible ingredients and maximum moisture content for flours, breads and rolls.

Specify minimum quality factors for many processed canned fruits and vegetables.

Specify the amount of food which must be in the container for many processed canned foods.

Standards have been established for a number of "enriched" foods, where it has been determined that the food is an appropriate carrier for the enrichment ingredients, and the general nutritional health would be served thereby. Federal standards do not require any basic food to be enriched; but they require that if the food is to be labeled as "enriched" it must contain the amounts and kinds of added enrichment ingredients called for by the standard, and no others. This saves the consumer the confusion which would result from a multiplicity of different types of enrichment for the same basic food, and the variety of unwarranted claims which would likely be made for them.

The FDA checks standardized foods, and particularly the enriched foods, to see that they comply with the standards.

Nutritional Quackery

During the past two decades the public has become increasingly nutrition-conscious, and particularly vitamin-conscious. This fact has been exploited by the promoters of the so-called health foods and the peddlers of certain vitamin-mineral type supplements. Despite the belief of most authorities that the *average* diet of a healthy American does not need supplementation with vitamins and minerals, it is now estimated that Americans spend $500 million a year for these products! This is due in large part to the lecture-hall pitchmen and door-to-door peddlers who hold their products out as practically cure-alls for the ills of mankind. While the products usually are not harmful in themselves, there is a danger that seriously ill persons may be led by these promoters to delay needed medical treatment, with the result that their conditions become more difficult, or perhaps impossible, to treat successfully.

The Food and Drug Administration is waging major campaigns, both educational and enforcement, against nutritional quackery. The American Medical Association, American Dietetic Association, and the National Better Business Bureau have joined in the educational campaign. The FDA has brought many court actions against false and misleading label claims for these products, and against products which were extravagantly promoted orally. But these cases are time-consuming and the FDA staff cannot deal adequately with the problem. Public education to dry up the market for over-promoted products not needed for supplementation of the adequate diet would seem to be the ultimate answer.

Nutritional Research

Several years ago a well known commercial infant formula was found to be causing convulsions in children for whom it was used as the complete diet. The product was recalled from the market, the formula changed on the basis of research by the company and marketing resumed. The illnesses occurred again, and again the product was withdrawn, the formula changed and the cycle repeated. Meantime, FDA scientists in the Division of Nutrition were busy with the problem. Working on a lead from earlier research only remotely related, an FDA scientist suggested that the commercial formula might be deficient in vitamin B_6, and that it was this deficiency that caused the illnesses reported. It was then demonstrated clinically[1] that injection of vitamin B_6 brought almost immediate recovery of infants in convulsion. Vitamin B_6 was added to the formula, and no further illnesses occurred.

More recently, a mysterious outbreak of disease in flocks of poultry caused the loss of several million birds on the East Coast and in the Middle West. Scientists in university and

commercial laboratories determined that the illnesses of poultry were caused by poultry feed containing a black, tarry residue left after several distillations of fat to obtain fatty acids.[2]

In order to determine whether a violation of the law had occurred, FDA scientists took up the investigation at this point. They have isolated experimentally a portion of the black tarry residue which will cause the disease in poultry and a different portion which is definitely toxic to rats. Investigation of the physiologic effects of the constituents of heated fats is being continued.

Research projects on requirements for vitamins and minerals, amino-acid composition and protein quality of food, relation of blood cholesterol to dietary changes, and utilization of various carbohydrates are examples that illustrate how law enforcement activities often contribute to nutritional and medical progress beyond the objective of law enforcement.

The Food and Drug Administration will welcome additional participation by physicians, nutritionists and dietitians in discussions of nutritional problems which arise in our law enforcement work.

CONCLUSION

Thus, the protection of the nutritional quality of our natural food supply is a part of the basic design of the Federal Food, Drug, and Cosmetic Act. The administration of the law to accomplish its objective becomes increasingly difficult and at the same time increasingly important as modern food technology develops new products and processes to meet the demands of our progressive society. Law enforcement can be no better than the scientific knowledge underlying it. Science must develop the facts with which to combat pseudoscience, and consumer education becomes more and more important. The Food and Drug Administration must have the support of the professional nutritionist if it is to be most effective in performing its own role in nutrition.

REFERENCES

1. Nelson, E. M. Association of vitamin B_6 deficiency with convulsions in infants. *Pub. Health Rep.*, 71: 445, 1956.
2. Friedman, L., Firestone, D., Horwitz, W., Banes, D., Anstead, M. K. and Shue, G. Studies of the chicken edema disease factor. *J. A. Official Agric. Chem.*, 42: 129, 1959.