FDA Nutrition Program

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The passage of the Food and Drugs Act of 1906, prohibiting adulteration and misbranding of foods, accelerated a consideration of their nutritive value and the advancement of nutrition science. In the first few years of the new law, the adulteration of foods involving the use of poisonous or deleterious ingredients was of primary importance. Foods containing toxic dyes and preservatives were common examples. As adulterated foods of this kind were driven from the market, greater attention was given to so-called economic types of adulteration such as the substitution of non-nutritive fillers, water, or other cheap ingredients for the more valuable food ingredients which the customer expected to find in the foods he purchased.

The knowledge of nutrition in those years did not permit the critical evaluation of the effects of processing and other manufacturing procedures on the nutritive value of our food supply that is commonplace today.

Since 1906, the science of nutrition has advanced more rapidly than in any prior period of time. It was not until the early part of the century that laboratory animals were used in testing the nutritional adequacy of foods. The word "vitamin" was coined in 1911, but it was not until 1926 that products were examined for vitamin content. The isolation, identification, and synthesis of the major vitamins took place in the decade from 1930 to 1940 when the importance of vitamins in our dietary was brought to the fore.

The enactment of the Food, Drug, and Cosmetic Act of 1938 reflected the progress that was being made in the field of nutrition and applied the new scientific knowledge to the protection of consumers. In addition to the basic adulteration and misbranding provisions of the Act of 1906, the 1938 law gave authority to establish legal standards for foods and thus provide for better control of the nutritive value of such products. It required more informative labeling of foods generally and authorized special labeling requirements for foods for special dietary uses.

The policies and regulatory actions of the Food and Drug Administration are designed to provide consumers with the benefits of practical application of reliable nutritional knowledge in the production and labeling of foods, and to prevent consumer exploitation by pseudo-nutritionists and other quacks.

A standard for a food under the Food, Drug, and Cosmetic Act must "promote honesty and fair dealing in the interest of consumers." Under this provision, consideration must be given to the effects of the kinds and amounts of ingredients permitted in a standardized food on its overall nutritional value. This has been of particular significance in considering proposals to add specific nutritive factors such as vitamins and minerals to staple foods.

Fortification of Foods

The Food and Drug Administration has followed a policy that is intended to limit the addition of specific nutritive ingredients such as

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vitamins and minerals to standardized foods to those instances where there is convincing nutritional evidence that the added nutrients will provide substantial benefits to significant segments of the population.

The addition to foods of specific nutrients already adequately supplied by unfortified common foods is not only wasteful but tends to confuse consumers as to their nutritional needs and the nutritional properties of our food supply.

The need for a basic Food and Drug Administration policy with respect to fortification of foods arose in connection with hearings in 1940 on standards for flour and related products. Many proposals to enrich flour with most of the known vitamins and many minerals were made by various proponents of the flour industry.

The FDA took the position that the addition of a vitamin to flour would not be desirable unless there was evidence that a substantial part of the population consumed a diet deficient in the vitamin in question. Such evidence might be deduced from dietary surveys or from clinical observations with respect to the occurrence of deficiency diseases.

It believed that it was also essential to know whether a food is a suitable vehicle for retention of the vitamin through any processes that may be necessary in preparing the food for consumption. It was important to know too that the fortified product would reach the population that was receiving a diet deficient in a particular vitamin.

If these conditions were met, it was important to add the vitamin in suitable quantities. If flour provided 25 percent of the calories ingested, it seemed proper to require that the quantity of flour consumed daily should contain at least one-fourth of the daily requirement of the vitamin used for fortification. There seemed to be no purpose in adding more than the daily requirement to this quantity.

The principles stated at the 1940 hearings have been generally accepted as the basis for fortifying flour. They have been used as a guide in subsequent proposals to fortify other foods, and they have received support from the Food and Nutrition Board of the National Research Council.

In accordance with a basic policy, legal standards for the following staple foods, containing added nutritive ingredients, have been established:

Enriched flour.
Enriched bread and rolls.
Enriched macaroni products.
Evaporated milk with increased vitamin D content.
Oleomargarine with added vitamin A.
Enriched corn products.

Standards for the same kind of foods without fortification have also been established. It will be noted that the Federal law does not require enrichment of these foods but leaves to manufacturers and consumers the freedom of choice to select the type desired. A schedule of sampling these standardized foods for vitamin, mineral, and other types of examination to determine compliance is a part of FDA regulatory operations.

Some Regulatory Programs

The degree of attention given to specific types of products will vary from year to year, based on experience and need for broader or more restricted coverage. Regulatory programs have also been developed to provide for the selective sampling for laboratory examination of the numerous vitamin and mineral supplements and other foods for special dietary uses. Since the facilities for laboratory examination of products bearing vitamin and other nutritional claims are limited, other regulatory programs have been developed to protect consumers from exploitation through false and misleading nutritional and therapeutic claims for such articles. These projects are designed to deal with representations which are unwarranted regardless of the nutritional properties of the particular products involved.

Misrepresentations concerning foods, and particularly vitamin and mineral preparations, are a difficult problem for the Food and Drug Administration. Much misinformation has been furnished the public about nutrition and its relation to health. Some of this stems from competition and attempts to gain a sales advantage through advertising and other promotional material based on recent scientific discoveries of undetermined or unestablished

significance. The substantial contribution to consumer misinformation and deception made by nutritional quacks and faddists cannot be overlooked.

An intensified program of consumer education by all those in a position to furnish scientifically sound information about nutrition is necessary to increase the effectiveness of the various Federal and State laws designed for consumer protection in this area.

The broad statement that the food of the American people does not furnish a satisfactory diet is frequently made. The contention is that our soils have been so depleted that they can no longer produce plants of adequate nutritive value or that chemical fertilization of crops has resulted in reduced nutritive value.

These pseudo-scientific statements have an aura of plausibility but little scientific justification.

To only a very small extent is the composition of the parts of plants that people eat governed by the composition of the soil. The composition of the plant and its nutritive properties is controlled primarily by genetic factors which also control its size and shape. Much is made of the destruction of vitamins in cooking and loss of vitamins and minerals when the water in which foods are cooked is thrown away. To be sure, there are losses of this kind, but the facts have been greatly overemphasized. Such losses have been greatly reduced by improved methods of cooking. One must remember that man began cooking his food a long time ago.

Nutritional deficiency diseases in the adult generally result from restricting the diet to a single food or to a very few foods rather than cooking losses. In the Orient, beriberi occurs among populations confined principally to a diet of polished rice. Pellagra and riboflavin deficiencies were observed in the southern part of this country, largely among people whose diets were restricted by their economic status to cornmeal, fatback, and molasses. Their diets have been improved both by changed economic conditions and by a food enrichment program with the result that vitamin deficiency diseases are now rarely seen in this country.

The similarity between the symptoms observed in human beings and other animals suffering from nutritional deficiencies and those resulting from non-nutritional causes has provided another fertile ground for exploitation of the consumer.

The extremely low incidence of demonstrable nutritional deficiency in this country has made it necessary for those with products to sell to talk in terms of "subclinical deficiencies" which, in less elegant language, means that the condition so described cannot be demonstrated to be of nutritional origin. This device, coupled with statements about the unreliability of our common food supply as a source of nutrients, because of soil erosion, cooking losses, and other similar misrepresentations, is typical of the misuses in which modern nutritional knowledge is being employed.

Foods for Special Dietary Uses

The Food, Drug, and Cosmetic Act recognizes the difficult and technical problems in the labeling of vitamin preparations and foods used in the management of disease. Section 403 (*j*) of the act gives the Secretary of the Department of Health, Education, and Welfare power to promulgate regulations to cover the labeling of those products. It also requires that the labels of vitamin preparations show the vitamin content. Section 403 (*j*) reads:

"A food shall be deemed to be misbranded if it purports to be or is represented for special dietary uses unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulation prescribes as, necessary in order fully to inform purchasers as to its value for such uses."

Biochemists generally regard vitamins as foods since they are essential nutrients, needed for growth and maintenance of the body. Only minute quantities are needed daily. Since pharmaceutical manufacturers have equipment and personnel trained to handle such small quantities, vitamin preparations ordinarily fall into drug channels for distribution and marketing.

Vitamins are usually measured in units, milligrams, or even micrograms—terms unfamiliar to many laymen. To meet the requirements that labeling for foods for special dietary use must fully inform the purchaser, "minimum daily requirements" have been established for vita-

mins. The vitamin content of a preparation must be stated on the label in terms of the proportion of the minimum daily requirement provided in the recommended daily intake. The quantities of the four minerals, iron, calcium, phosphorus, and iodine, which before 1940 were the most frequently used supplements to the daily diet, must also be declared in the same manner.

Infant foods must be labeled to show all ingredients. Since the feeding of infants often presents problems, it is important that infant foods bear all the information necessary for their use. Labels of other foods are not required to name the spices, flavorings, or coloring material present. The label of a product that is a complete or partial substitute for human milk must state that additional quantities of vitamins C and D and of iron must be supplied from other sources if the quantities present are not adequate. The label must bear a quantitative declaration of vitamins A, B_1, C, and D, and must list the percentages by weight of water, protein, fat, available carbohydrates, crude fiber, calcium, phosphate, and iron.

Many foods are offered for control of body weight, particularly by reducing. The label of a food for the control of body weight or the dietary management of disease must state the percentages by weight of protein, fat, and of available carbohydrates as well as the number of available calories in a specified quantity.

If crude fiber is represented to be of significance in a food, the percentage by weight must be declared on the label. If saccharine or a saccharine salt is used in a food in lieu of sugar, the label must bear the statement, "Contains -- saccharine (or saccharine salt, as the case may be), a non-nutritive artificial sweetener which should be used only by persons who must limit their intake of ordinary sweets." The weight of saccharine or saccharine salt is inserted in the blank.

If a food is for special dietary use because of reduced allergenic properties, the label must bear the common or usual name of each ingredient, including any spice, flavoring, or coloring used. The label must also contain a statement indicating the nature and effect of any process to change the allergenic properties of the food or its ingredients.

All of these requirements are contained in the food and drug regulations promulgated in 1941. The regulations have served their purpose well, but now they are somewhat outdated and in need of revision and extension.

A few years ago the labeling of foods with reduced sodium content became an important problem. It was shown that a reduced sodium intake was more important in the control of blood pressure than had been realized. Many foods on the market labeled "No salt added" contained considerable quantities of sodium from other sources although it was a statement of fact that no salt had been added. Some contained considerable amounts of sodium as a natural constituent. Sodium glutamate, which is used extensively for flavoring, and sodium propionate, which is an effective mold inhibitor, may contribute unsuitable quantities of sodium.

Foods labeled "No salt added" are attractive to a person seeking low sodium foods, but they have little value for the purpose desired. Such representations are, of course, misleading. There are a number of ways in which foods may pick up sodium in the process of manufacture, and producers of foods that are offered for the benefit of persons on a low sodium diet should determine the actual sodium content of the food.

The regulations require that if a food is represented to be of value because of a low sodium or low salt content, it must be labeled to show its sodium content in milligrams per hundred grams of food as well as per serving.

The Division of Nutrition

The Division of Nutrition of the Food and Drug Administration is responsible for the development of scientific facts and opinions concerning nutrition as a basis for the policies and regulatory activities of the FDA. It also examines official samples for vitamin or other nutritional properties, by means of biological, microbiological, or chemical procedures which cannot be performed in the field laboratories of the FDA.

Under normal circumstances, the division's work is about equally divided between strictly enforcement operations and specialized research designed to facilitate or improve FDA enforcement of the Federal Food, Drug,

and Cosmetic Act. Research activities of the division have been limited almost entirely to the development or improvement of assay procedures for enforcement purposes. There is little incentive to do this kind of research in other nutrition laboratories. Such research has made possible a more rapid and precise examination of a greater number of samples without an increase in manpower.

The manufacturers of vitamin preparations have a very similar problem, and there has been excellent cooperation with industry laboratories in the study and development of control methods.

It is necessary that the Division of Nutrition keep abreast of the scientific developments in the field of nutrition. This is accomplished by a study of the scientific literature, communications and consultation with outside authorities in the field, and by attendance and participation in the activities of scientific societies and associations. It must also be alert for developments in manufacturing and labeling practices which may require changes in policies and regulatory activities in order to recommend such changes to the Commissioner of Food and Drugs.

In the case of litigation involving products examined in its laboratory, the division must be prepared to provide convincing scientific evidence of the deficiency suitable for presentation in the Federal courts. The division's analysts who are called upon to provide such testimony must be so qualified by training and experience that their evidence can successfully withstand cross examination.

In cases involving false and misleading claims about the nutritive or therapeutic value of vitamins, minerals, and other food factors, various members of the Division of Nutrition are called upon to testify as experts and must therefore be prepared to qualify as such in court. Among other things, they must have a comprehensive knowledge of the views of other experts in the field so that they may testify as to what constitutes the consensus of scientific authorities in the field of inquiry. Such qualifications are likewise of utmost importance to the work of the Food and Drug Administration, to the end that its actions and policies will be in accord with the best scientific knowledge available and enjoy the support of the outstanding authorities in the field of nutrition.

Fourth Annual Symposium on Antibiotics

The Fourth Annual Symposium on Antibiotics, sponsored by the Division of Antibiotics of the Food and Drug Administration, Department of Health, Education, and Welfare, with the journals, *Antibiotics and Chemotherapy* and *Antibiotic Medicine & Clinical Chemotherapy* will be held on October 17–19, 1956, at the Willard Hotel, 14th Street and Pennsylvania Avenue, NW., Washington, D. C.

To allow the program committee time to review material for presentation and to facilitate publication of the Antibiotics Annual 1956–57, manuscripts must be submitted by September 17, 1956.

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