

GOVERNMENTAL CONTROL PROBLEMS IN THE FORTIFICATION OF FOODS WITH VITAMINS AND MINERALS

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PRACTICALLY all aspects of the desirability of fortifying foods with vitamins or minerals have long been problems of the Food and Drug Administration. These problems have arisen in considering the propriety of the representations that have been made for various vitamin and mineral preparations. Successful sales promotion of such products depends on the extent to which representations can be made that our dietaries do not supply certain food essentials in adequate amounts. It also depends on the representations made with respect to the nature of the ills or conditions which result from such deficiencies. Much has been published on the subject of nutrition in recent years and quite diverse opinions have been expressed. It is necessary for one to be rather circumspect in arriving at a conclusion, or even an opinion, with respect to the value of minerals and vitamins. If one surveys the literature with a view to determining what possible beneficial effects may be expected by increasing the vitamin or mineral content of our foods, he arrives at one opinion. He arrives at an entirely different opinion with respect to their value if he reviews the literature with a view to determining just how much has been definitely established. I could say that this is due to a paucity of established facts, if I could be generous enough to overlook altogether too many statements in scientific literature that reflect a degree of optimism concerning what vitamins can accomplish that is not fully warranted by experimental or clinical evidence. I would have no difficulty in preparing a brochure consisting practically entirely of quotations from scien-

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tific literature which would appear to form a convincing case for extensive deficiency in our dietaries of vitamin A, B, C, or D, or the minerals calcium, phosphorus, iron, or iodine. It could also be shown that a great many of our ailments are due specifically to a deficiency of each of these substances. There is inadequate information concerning the vitamin content of foods actually consumed. Human requirements for vitamins and minerals are not well established. We do not have satisfactory criteria for determining objectively lesser deficiencies which do not produce definite manifestations of specific diseases. Since we do not have adequate information and a decision must be based on individual judgment, humanitarian principles dictate that if there is a possibility of error, we should not err in a direction which may add further to possible human suffering, because the existence or importance of certain inadequacies of diets are not definitely established.

The legislative acts enforced by the Food and Drug Administration do not prohibit the fortification of foods with vitamins or minerals. They do prohibit unwarranted representations for such products. The responsibility of the Food and Drug Administration with respect to representations for foods is limited to the labeling of goods in interstate commerce or importations. This responsibility is voiced in the Federal Food and Drugs Act of 1906 and the Food, Drug, and Cosmetic Act, which is scheduled to become fully effective on June 25th of this year. Authority for the control of advertising for food, drug, and cosmetic preparations has been conferred upon the Federal Trade Commission by the Wheeler-Lea Act, which was passed in 1938. There are some sections of the Food, Drug, and Cosmetic Act which have an immediate bearing on the subject of this symposium. If it is agreed that from the standpoint of protection of public health there is need for the fortification of foods with vitamins or minerals, then it becomes important to know to what extent existing statutes will be an aid or a hindrance in effective distribution and sale of such products. We also want to

know to what extent it is necessary for manufacturers to give the purchaser helpful information.

The Food, Drug, and Cosmetic Act provides for promulgation of definitions and standards for foods whenever this is deemed to promote honesty and fair dealing in the interest of consumers. Whenever a definition and standard has been adopted for a food, that name must be used on the label, and use of the name for that product signifies that it conforms with the definition and standard. It is obvious that there are many foods which are of natural origin or manufactured by standardized processes, all of which are readily identified by common names, but it is necessary to have legal standards for the composition of such products to prevent their sophistication and to have means of preventing undesirable trade practices.

If a definition and standard has not been promulgated for a food and it is fabricated from two or more ingredients, the law requires that the label bear a list of the ingredients by their common or usual name. It will certainly be a revelation to some people to find out that combinations of simple foods have been represented to be helpful or beneficial in preventing various diseases, improving digestive processes, increasing or reducing weight, increasing attractiveness of the figure, improving the texture of the skin, producing sexual vigor, quieting the nerves, and veritably giving comfort to the soul.

Of further importance is the following section: "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 regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses." There is no similar requirement with respect to informative labeling in the Food and Drugs Act of 1906. Please note that this section is entirely ineffective unless regulations have been prescribed. We are now engaged in drafting such regulations, and we welcome any suggestions with respect to how the intent and purpose of this sec-

tion can best be accomplished. The following procedure must be followed in the promulgation of regulations: The Secretary of Agriculture must give appropriate notice of a hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a hearing to be held not less than thirty days after the date of notice. At the hearing any interested person may be heard in person or by his representative. The hearings are held before a presiding officer appointed by the Secretary. After the hearings have been held, the presiding officer prepares a statement of the proposed findings of fact and proposed regulations, which are subject to review by an appellate court if there is a basis for controversy or if a person can show that he will be adversely affected by the proposed regulations.

There is no definition of the term "food for special dietary uses," but it appears to us that it certainly was the intention to include foods fortified with vitamins or minerals under this section. A provision requiring statements on the label which fully inform the purchaser obviously makes it possible to require statements which set forth the limitations of the value of a product, as well as to state in terms that are readily understood the quantity of vitamins or minerals present. The fact that a product may be considered a food for special dietary use does not release it from the obligation of listing ingredients by their usual or common name.

Extensive fortification of foods may possibly lead to increased and more difficult problems of control from the standpoint of assuring the consumer that the product has the vitamin content claimed. That, however, should be no deterrent if there is satisfactory evidence that an important portion of our population would benefit from such vitamin additions to staple food products. It is important that if fortification is recommended, such fortification be substantial so that the product has an identity which will definitely distinguish it from the same product without fortification. I may use tomato juice as an example. Let us assume that the vita-

min C content of tomato juice varies from 12 to 30 milligrams per 100 cc. with an average of 18 milligrams. If tomato juice were to be fortified with vitamin C—and I will interject that such fortification seems entirely unnecessary—the vitamin C content of the fortified product should be definitely higher than the vitamin C content of any tomato juice that has not been fortified.

In our control work we are conscious of an extensive, rapidly growing, and constantly changing industry in vitamin preparations. Changes are frequently brought about by new discoveries which may be accompanied by the issuance of patents. There are at present patents which relate to the synthesis or manufacture of preparations of vitamins A, B₁, C, and D suitable for incorporation in foods.

It is difficult to obtain accurate figures of the vitamin industry in this country, but I shall try to provide you with a few that may serve to give you at least a partial picture. According to available statistics more than 95 per cent of the cod liver oil used in this country is imported. Importations for 1938 totaled more than five million gallons. More than half of this oil is used for animal feeding, but an estimate that two million gallons were used for human consumption seems conservative. If this oil retailed at \$1.00 per pint, its total cost to the consumer would be \$16,000,000. A considerable portion of this oil is used for the manufacture of concentrates of vitamins A and D, which may be consumed as such or put into capsules, tablets, or so-called tonic preparations. These manufacturing processes increase the cost of the vitamins to the consumer. During the past year more than \$30,000,000 was spent by consumers for vitamin preparations put up in gelatin capsules. Figures released by the Bureau of the Census of the Department of Commerce show that there was a five-fold increase in the manufacture of vitamin preparations made for sale directly to the public and which can be classified as U. S. Pharmacopoeia or National Formulary articles, in the two years from 1935 to 1937. During the same

period there was only a slight increase in the value of products manufactured which were intended for direct sale to or prescribed by the physician. The total value of the manufactured products for the year 1937 was in excess of \$26,000,000. These figures are the value of the products as manufactured and not the cost to the consumer. To this must be added the cost of advertising, transportation, and profits of the manufacturer, the wholesale merchant, and the retailer. On the basis of the figures I have quoted and other information available to me, I have reason to believe that during the year 1938 the people of the United States spent more than \$100,000,000 for vitamin preparations manufactured or sold through pharmaceutical channels. This is approximately \$1.00 per person for every man, woman, and child in this country.

From the nature of the program I anticipate that the need for the actual fortification of foods will be adequately discussed this evening by other speakers. However, I would like to make a few observations. Surveys which have been made indicate that if there are deficiencies of vitamins or minerals in an important proportion of our population, such deficiencies are most likely to occur among the low-income groups. Any program of fortification will not serve its most useful purpose unless these groups are given prime consideration. Much too frequently generalizations with respect to vitamin or mineral deficiencies are found to be in error. It is a fact that, generally speaking, our foods are deficient in vitamin D. Nevertheless, since beneficial effects of vitamin D can be obtained by exposure to sunshine, it is equally true that for a large area of the United States no beneficial effects can be expected from the addition of vitamin D to foods. In spite of this fact we have seen an advertising campaign conducted for the use of vitamin D milk in Miami, Florida. It is the opinion of a number of authorities in the field of nutrition that our dietaries may be low in calcium. Yet there are extensive areas of the United States where calcium deficiency is not likely to occur. Not only should each vitamin or mineral be

considered independently, but the desirability of fortifying specific foods should also be considered independently. In trying to reach a decision with respect to the desirability of fortifying a particular food or class of foods with one of the vitamins or one of the minerals, it may be well to bear in mind that a statement justifying the fortification of a food with vitamin B₁, for example, may be used to the same advantage in promoting the sale of a vitamin B₁ preparation. I make note of this because writers have frequently emphasized the need for a certain food essential in a manner that inadvertently places them in a position of making a general recommendation. In this connection I can do no better than quote the last two sentences of a paper by H. H. Mitchell:

“ . . . At a time when popular periodicals are widely publishing irresponsible articles on vitamins, ignorantly, or deliberately creating an entirely distorted popular conception of them, and when commercial concerns are widely advertising purely hypothetical advantages of vitamin preparations, it is particularly important that investigators in nutrition exert great care in the wording of statements as to the practical significance of vitamins in every-day life. Otherwise they may become unwilling accomplices in the perpetration of a gigantic fraud upon the American public.”

This statement was published in *Science* in July 1922, and it is in my opinion equally applicable at the present time.