

THE PUBLIC HEALTH ASPECTS OF THE FORTIFICATION OF FOODS WITH VITAMINS AND MINERALS

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THE question of the desirability of fortifying foods with vitamins and minerals from the point of view of public health or preventive medicine is a most important one because the principal, if not the only possible reason for doing this is the prevention of deficiency diseases. I can see no other valid reason for even considering the question. By no stretch of the imagination can such a procedure be considered desirable in the treatment of disease. Surely we can all agree that the treatment of the vitamin deficiency diseases can be most satisfactorily carried out by the use of concentrated vitamin preparations properly administered in the hands of qualified physicians. The one legitimate reason, then, for fortifying foods with vitamins and minerals is to prevent disease, and it is from this point of view that we should examine the problem. There are several important questions we should ask ourselves in this connection—such as—is it practical, is it economical, is it efficient, is it safe, and, above all, is it the best method for us to use in attacking the problem of the prevention of our deficiency diseases?

At this point I want to make a special exception for the case of the fortification of milk with vitamin D for children in certain areas. Because of our inability properly to expose the skin of infants to direct sunlight at all seasons of the year, increasing the vitamin D content of cow's milk for infants in some areas appears to be one of the most satisfactory means of preventing rickets. Although this procedure is subject to many of the objections to fortifying any

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food, the fact that it enables us to offer vitamin D in a form in which it will be given to infants more than offsets all the arguments against it. I therefore feel that this is a special case which in itself makes it undesirable to add vitamin D to other foods.

Let us then try to answer some of the questions I mentioned a moment ago in regard to fortifying all other foods with vitamins and minerals.

In the study of preventive medicine we are taught that certain basic information must be available before an effective effort can be made to prevent any disease. It is fundamental that we must know first whether the disease in question is present and, if so, to what extent. We also must know where the disease is located, what its cause is, and what part of the population is most seriously affected by it. Without such information one cannot even begin to adequately prevent and control any disease, and it is the lack of just such information that has seriously handicapped us in our efforts to prevent the deficiency diseases. We do have some of the necessary information. We know that dietary deficiency diseases exist in the United States. We have plenty of rickets, scurvy, pellagra, and nutritional anemia, among other things. However, we do not know to what extent any of these diseases occur, and we do not know where the cases are located. In addition, there is absolutely no adequate information available on the prevalence of the so-called subclinical stages of the various vitamin deficiency diseases. The fact that we cannot state with accuracy either the number of cases of vitamin deficiency diseases occurring each year or where they occur might erroneously lead one to the conclusion that this constitutes a good reason for trying to prevent these diseases by fortifying commonly-used foods with vitamins and minerals. This is a method similar to that condemned years ago by the medical profession as the "shot-gun" method of treatment. By scattering your vitamin shots over the entire population you hope that a few pellets will hit the individuals needing them. Unfortunately, this method does not

cover the possibility of your pointing the gun in the wrong direction and missing the bird entirely, because by fortifying foods with vitamins you increase their cost and move them farther than ever from the reach of the population group needing them most seriously.

Although, as I have indicated, our accurate knowledge about the occurrence of the deficiency diseases is meager, we do have much information which leads us to make worth-while estimates about conditions. For example, no one will question that our pellagra problem is primarily one of the southern United States, while our rickets is a more serious problem in our northern and northeastern sections. Therefore, we can make a crude geographic location of two of our most serious vitamin deficiency diseases. But much more important than this is the evidence that has accumulated on the relationship between the deficiency diseases and income. Goldberger, many years ago, showed a direct relationship between income and the incidence of pellagra in the South, and more recently many studies, but especially the extensive work of Stiebeling and her associates in the United States, have shown very clearly that the lower the income the greater is the probability that a family will obtain an inadequate diet. I think we are justified, therefore, in locating our public health problem in the prevention of the dietary deficiency diseases in that section of the population with the lowest income in any given area.

Now, then, since our purpose in fortifying foods with vitamins is the prevention of these diseases, it is certainly this low-income group that needs our vitamin-fortified foods, and what are we doing? Actually, we are making it more difficult for them to obtain these foods for there can be no question but that the addition of vitamins to foods will increase the cost, and every penny added to the cost of food simply places it farther than ever away from this lowest income group which is receiving a deficient diet because the cost of the unfortified foods is already beyond their means. We

should be devoting our efforts to decreasing the cost of food for this group rather than increasing it.

The fortification of foods with vitamins and minerals, then, in all probability would not only fail to be of any material value in the prevention of the deficiency diseases by not reaching the population group in greatest need of them, but it also would be an economically wasteful procedure, since it unnecessarily increases the cost of these foods to people whose diet is already adequate and who might be persuaded to buy these fortified foods although not needing them.

I have already indicated that a procedure such as this must be regarded as bad preventive medical practice, but there are still other points to be considered. It is becoming increasingly clear that multiple deficiency diseases are the rule rather than the exception. A patient suffering from, say, pellagra, rickets, or scurvy, is quite likely to have symptoms of some other deficiency at the same time. There is really no reason to expect an inadequate diet to be deficient in only one respect. Those of you who have had occasion to study deficient diets as they are found in the field no doubt wonder how some people have escaped having two or three deficiency diseases simultaneously. This situation raises the question of which vitamins and minerals shall we use to fortify foods—if we are going to use any? And this in turn raises a whole host of unanswerable questions. How much shall we add? To what foods shall we add them? Shall we add some to one food and some to another? How will we be able to tell when we have the right amount of the right combination? No one food can have a monopoly and we can expect a variety of foods to be fortified if this procedure is encouraged. Yet, we certainly don't want our meals supercharged with a load of vitamins A to P and minerals aluminum to zirconium. This would not only be unnecessary and wasteful, but we might even become so big and strong and vigorous and youthful that we might want to start a war with somebody. Seriously, though, we should not dismiss too lightly the possibility of harm from overdoses of

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vitamins. Although there is no evidence of immediate harm from relatively large excesses, long-time experiments over several generations have not been carried out, and we should also keep in mind the observations of McCay and his associates that animals that grow to maturity slowly live longer than those that mature rapidly.

I think we can safely say that there are so many unknown factors involved in both the question of what to add and how much of each to use in fortifying a food that it would be prudent not to undertake it at this time as a public health measure.

Finally, to me it does seem a little ridiculous to take a natural foodstuff in which the vitamins and minerals have been placed by nature, submit this foodstuff to a refining process which removes them, and then add them back to the refined product at an increased cost. Yet this seems to be the thing that is being proposed. If this is the object, why not follow the cheaper, more sensible, and nutritionally more desirable procedure of simply using the unrefined, or at the most, slightly refined natural food?

Unfortunately, we must face the existing situation that certain refined foods are our cheapest sources of food energy and that there is a public desire for white foods with a background which is difficult to break down, particularly among the uneducated. Instead of attempting to correct the situation by fortifying these foods at increased cost, it seems better procedure to me to try to build up an association between good health and a colorful diet. A diet that has a lot of red, yellow, orange, and green color from natural foods is not likely to be deficient in minerals or vitamins.

It is granted that the use of some refined foods is desirable, but it is indeed an anomaly to find that there is little or no difference in the retail price between some refined foods and the same food unrefined. For example, brown rice retails in Washington, D. C., for the same price as polished rice.

I do not believe that our deficiency disease problem will ever be solved by fortifying foods, but it can be solved by education and

by making available to all classes the widest variety of natural, unrefined foods at the lowest possible prices.

Stiebeling's investigations show that even today in the groups spending small sums of money for food a small proportion of the families, by wise spending, are able to obtain an adequate diet. This in itself shows the solution to the problem. I, for one, would certainly never advocate among that group of people the spending of one extra dime for a refined food fortified with vitamins and minerals.

Let us consider for a moment the reasons why we have deficiency diseases. Broadly, they are our needless refining of foods and the inability of our lowest economic groups to obtain a varied diet, either through ignorance or economic causes.

Let us take an example of a public health problem in this field. It is common experience for the southern health officer to find himself confronted with a considerable number of cases of pellagra. This is a problem in treatment which is handled by the local physicians and the health officer in the best way they can. The question here is: How can this health officer prevent future outbreaks in his community? Should he introduce some food fortified with nicotinic acid or should he attempt to get his population to eat a more varied diet which will afford protection against pellagra? In my mind there is no question as to the preference for the latter method, because by so doing he also prevents the other vitamin deficiency diseases. Or, to take as another example, the recent attention which has been given to scurvy in Maine. The health officer, in meeting the situation, rightly chose to attempt to obtain a supply of citrus fruits and encourage their use rather than use food fortified with ascorbic acid.

Unfortunately, there seems to be some quirk in most of us that makes us want to take a pill. There is something rather final and satisfying after swallowing a pill. After it passes that final obstruction on the way down we are inclined to mentally compose our-

selves to await a miraculous and completely curative result. I am afraid there is much of that psychology behind the fortification of foods with vitamins. I am afraid also that we are beginning to look on food and eating more as a duty than a pleasure. We are so accustomed to the association of illness with unpleasant medicine that it seems difficult to even put across the idea that here is a whole group of diseases that require no pills, no unpleasantness to prevent, and that their prevention can actually be made a most agreeable occupation or even recreation. But this is too simple. I am reminded of the story current down South about the negro who, on being given his first package of debittered brewers yeast, returned to the health department and asked for more of the bitter yeast because the new yeast didn't taste strong enough. The association between disease and medicine is so firmly fixed in the mind of the public that one is looked on with a certain degree of suspicion if you say that all the treatment that is necessary is a variety of nice, fresh vegetables, eggs, meats, milk, and so forth. As a public health measure, I think we should actively oppose the fortification of foods with vitamins and, instead, we should do all in our power to destroy this misconception in the public mind that such things are necessary to prevent the deficiency diseases.

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.