Editorial

Should Vitamin-Mineral Products Be Standardized?

The Food and Nutrition Board of the National Research Council has been requested by the Food and Drug Administration to provide answers to certain questions in regard to the use of vitamin-mineral products, including the desirability of establishing standards for such products. The National Research Council (Food and Nutrition Board) has been reported to have accepted this commission and the Executive Committee of the Board is reported to have a draft of reply under consideration. Since the questions raised indicate that the Food and Drug Administration is dissatisfied with the present labeling situation and desires a better system of control, and since the answers to these questions could very well drastically affect the availability and utilization of vitamin-mineral products, we are taking this editorial space to bring these questions to your attention, along with our answers.

Question: Are there conditions which make it necessary or desirable to supplement the diet with certain combinations of vitamins?

Answer: Yes.

Question: If the answer to this question is yes, what are these conditions and what vitamins are needed for these purposes?

Answer: The conditions which make vitamin supplementation necessary include: Poor dietary habits, unavailability of certain foods, diminished intake of certain foods for any reason, interference with intestinal absorption or the destruction of vitamins in the intestinal tract, increased metabolic requirements, impairment in utilization or storage, and increased loss or excretion of nutrients from the body. The vitamins and minerals needed for the management of these conditions will vary from condition to condition and with various diets.

Question: To meet such needs, what quantities of vitamins should be supplied in a daily supplement?

Answer: The amounts needed as a daily supplement vary widely. In general, supplemental vitamin requirements can be met within a range of one-quarter to three times the Recommended Dietary Allowances.

Question: Should the quantity of each vitamin be related to the quantity of that vitamin necessary to meet normal requirements?

Answer: In general, vitamin and/or mineral mixtures designed to supplement inadequate diets should bear some relation to the daily requirements. However, the quantity of any particular vitamin or mineral in vitamin-mineral preparations should also bear some relation to the probable adequacy or inadequacy of that vitamin or mineral in the diet of the individuals for whom the product is intended. Also, since supplemental vitamin preparations are often intended for the use of individuals with greater than normal requirements, provision must be made for products containing greater amounts of certain vitamins than the Recommended Dietary Allowances. In other instances it may be desirable to omit certain vitamins from multiple vitamin preparations, i.e., individuals with leukemia may require vitamin supplements from which folic acid has been omitted.

Question: Will the establishment of standards help in preventing the consumer from being

misled by representations made for products of the type now on the market?

Answer: Pharmaceutical vitamin preparations are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and are properly classified as drugs. As such, the Food and Drug Administration has no authority to establish standards of identity. In order to do so, the Food and Drug Administration would have to classify pharmaceutical vitamin preparations as foods, and there is some doubt that the Food and Drug Administration has authority to do this under the present Food, Drug, and Cosmetic Act. There is no reason to believe that establishing standards would help in preventing the consumer from being misled. The present labeling requirements are for practical purposes adequate to protect the consumer. The nefarious practices which appear to concern the Food and Drug Administration involve a very small minority of the industry, less than 5 per cent of the total pharmaceutical vitamin and mineral sales. The answer to this problem lies in strengthening the Federal Trade Commission and not in placing 95 per cent of the pharmaceutical industry in a regulatory straight-jacket that will still leave the offending minority just as free to make improper claims for their products. There is no problem of safety involved in the sale of supplemental vitamin and/or mineral products. The problem of adulteration is covered by the Federal Food, Drug, and Cosmetic Act. The problem of false or misleading claims is covered, in labeling, by the Food, Drug, and Cosmetic Act; and, in advertising, by the Federal Trade Commission Act.

Question: Will the establishment of standards stand in the way of progress in proper use of vitamins?

Answer: If the Food and Drug Administration is allowed to decree specific formulae for vitamin preparations, both as to what may be contained therein and how much of each ingredient, it will tend to discourage the development and utilization of new vitamins and minerals and will result in the discontinuance of many useful combinations. It will deprive the physician of ready-made combinations and interfere with his professional prerogative to choose from a wide variety of medicines. The medical profession should strongly resist efforts to standardize the medication which they may prescribe. The standardization of vitamin formulae by the Food and Drug Administration would discourage research by the industry and would impede the progress of the science of nutrition.

At this time it is pertinent also to point out that there is absolutely no indication or justification for the Food and Drug Administration to make therapeutic vitamin preparations prescription items. Doing so would simply needlessly increase their cost and lessen their use.

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