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Dietary Supplements : Current Controversies in the United States

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ABSTRACT

Dietary supplements are generally defined as concentrated sources of nutrients prescribed in addition to the daily diet to increase nutrient intake. These supplements are usually in the form of tablets, capsules, pills, powders, or liquids. Sales of dietary supplements are roughly $4 billion per year in the United States. Nearly 4 out of every 10 adults use dietary supplements regularly. This article is to report the pros and cons in the use of dietary supplements and a brief overview of current law, proposed regulations, and related activities in the United States. It provides what information should be known to the public before federal regulations governing health claims are made. These regulations may decide whether health food industries or pharmaceutical companies can make claims about the function of nutrients. (*Korean J Nutrition* 30(6) : 727~732, 1997)

KEY WORDS : dietary supplements · controversies · regulation.

Introduction

A definition for dietary supplements is a general term that usually refers to a concentrated source of nutrients prescribed in addition to the daily diet to increase nutrient intake[1]. A supplement may be a food such as yeast or wheat germ, a concentrate such as cod liver oil, or pharmaceutical preparation of amino acids, vitamins or minerals, herbs and botanicals, and any dietary substances that are sold as tablets, capsules, pills, powders, or liquids[2][3]. The efficacy of such use, or even the need for intake above that supplied by diet alone, has been the source of considerable controversy in the medical and scientific fields.

In spite of the controversy regarding supplement usage, it has become fairly wide spread[4]. This article describes current controversies and recent regulations on dietary supplements in the United States.

1. What are the pros and cons of the use of dietary supplements?

In a survey of college students in Arizona, 37% of the respondents were reported to use supplements weekly or daily, while 25% took supplements less than once per week[2]. In support of supplements, some users believe that food supplements increase pep and energy, reduce stress, and decrease incidence to or severity of health problems. Supplemental intakes of the antioxidant vitamins(vitamins A, C, E, and β-carotene) have been shown to reduce the risk of specific types of cancers and cardiovascular diseases[5]. Some users advocate a multinutrient preparation and/or use of more specific individual micronutrients, with a liberal view that harm will not likely occur. They seem to think that these products are nutritional magic bullets for cancer, heart disease, and other maladies.

Certain nutrients are most often found to be deficient in meeting the American Recommended Dietary Allowances(RDAs) for folic acid, vitamin B6, magnesium, zinc, calcium, iron, and the carotenoid source of vitamin A[6]. Food fortification is used to remedy these deficiencies, in particular the full restoration of

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Table 1. Circumstances affecting nutrient status*

Circumstances	Population affected
1. Poor dietary intake	Dieters
	Individuals on very low calorie diets
	Seniors
	Strict vegetarians
	Food faddists
	Chronic alcohol users
	Adolescents(especially, anorexia nervosa and bulimia)
2. Altered absorption, utilization, or excretion	Long-term medication users
	Chronic alcohol users
	Individuals with long-term illness or chronic stress
	Women with heavy menstruation and postmenopause
3. Increased needs	Pregnant and lactating women
	Adolescents
	Tobacco users
	Individuals with chronic illness
	Stress

*Reference 7)

nutrient losses attributable to the refinement of wheat, corn, and rice flour. The supplementation of antioxidant nutrients in a multinutrient preparation or separate antioxidant preparation not exceeding recommended dietary levels would have highly significant benefits with minimum harm and at a very low cost.

The typical unbalanced diet contains too much total fat, saturated fat, cholesterol, protein, sugar, and salt and not enough complex carbohydrates, fibers, fruits, vegetables, vitamins, and minerals[7]. The following population groups are at the highest risk for nutritional deficiencies and may have the greatest benefit from supplementation : the malnourished, people with certain increased needs, and those with conditions of altered absorbtion, excretion, or utilization (Table 1).

Despite the fact that the use of dietary supplements is a very common practice in the United States, some people think that healthy individuals should be able to meet all of their nutrient needs with diet rather than with supplemental vitamins and minerals[2]. It is thought that food is the appropriate source for nutrients and that recommendations to supplement could result in the mistaken belief that supplements can substitute for a healthy diet. Other health professionals note that clinical deficiencies of vitamins and minerals are extremely rare in the United States today and, therefore, supplements are not needed to prevent deficiencies[7].

More is better could lead to over-consumption of some micronutrients leading to a waste of money at best. At worst, some nutrients can be stored to a potentially toxic level. For example, all fat-soluble vitamins are potentially toxic due to any excesses being stored. In the past, all water-soluble vitamins were considered safe at any dosage, any excesses being excreted. The latest research, however, indicates that even some water-soluble vitamins like niacin, vitamin B6, folacin, and pantothenic acid may be stored in the body(Table 2).

Another concern with supplements is the possibility of adverse nutrient interactions. Calcium, for example, may affect the absorption of iron and vice versa. Also, various amino acids can potentially compete with each other's absorption in the small intestine[9].

When considering only nutrients that fall into the US RDA category, the latest report of Dietary Guidelines for Americans states that diets that meet RDAs are almost certain to ensure intakes of enough essential nutrients by most healthy people[10]. However, for all the additional categories of supplements such as herbs and botanicals, and any dietary substances that are sold as tablets, capsules, pills, powders, or liquids, these areas are still open to investigation for health claims and benefits.

Table 2. Vitamin and mineral safety issues*

Nutrient	US RDA	Toxic dose	Symptoms
Vitamin A	5,000IU	50,000 – 500,000IU	Chronic ingestion of lesser amounts can cause headache and nausea while a single extremely high dose can cause acute, reversible effects
Beta-carotene	10 – 30mg**	————	High intake not associated with any toxicity symptoms. Hypercarotenemia(harmless yellowing of the skin) might occur with high intake
Vitamin D	400IU	25,000 – 200,000IU	Nausea, vomiting, loss of appetite, dry mouth, headache, and dizziness can occur
Vitamin E	30IU	3,000 IU	Safe, even with prolonged, high intakes. Individuals on anticoagulants should avoid doses above 400 IU
Vitamin B1	1.5mg	————	Excess cleared by the kidneys, generally considered safe at all intake levels
Vitamin B2	1.7mg	————	No reported toxic effects
Niacin	20mg	300 – 600mg	Headache, nausea, and skin(niacinamide form) blotching can occur. Flushing, rashes, tingling(nicotinic acid form) and itching can occur. Doses exceeding 2.5grams/day can cause liver damage and glucose intolerance
Vitamin B6	2mg	250 – 1,000mg	Prolonged high doses can cause reversible nerve damage
Vitamin B12	4mcg	————	No reported toxic effects
Folacin	400mcg	400 – 1,000mcg	Safe up to 15mg. However, lower doses can increase excretion of zinc and mask symptoms of vitamin B12 deficiency
Pantothenic acid	10mg	10 – 20g	Generally safe at high doses ; can produce diarrhea and water retention
Vitamin C	60mg	1,000 – 5,000mg	Some research shows no toxicity at intakes as high as 10,000mg/day. Doses as low as 1,000 – 2,000mg might contribute to kidney stones, mineral interaction, impaired immune function, and withdrawal symptoms
Calcium	1,000mg	3,000 – 8,000mg	Numerous adverse symptoms, including nausea, vomiting, high blood pressure, diarrhea, constipation, and milk-alkali symptom
Chromium	50 – 200mcg***	————	No known or reported toxic effects
Copper	2mg	————	Nausea, vomiting, headache, jaundice
Iron	18mg	18+mg	Constipation and stomach upset can occur. Doses above 100mg daily can result in abdominal pain, fatigue, weight loss, and possibly heart disease
Magnesium	400mg	1,000+mg	Diarrhea, low blood pressure, and nausea can occur
Selenium	50 – 200mcg***	800 – 3,000mcg	Brittle hair and fingernails, dizziness, fatigue, nausea, diarrhea, and liver disease can occur
Zinc	15mg	50 – 150mg	Can interfere with copper absorption, lower HDL-cholesterol, impair immune response, and cause dizziness, vomiting and anemia

*Reference[8]
**There is no established RDA for beta-carotene. This intake level is recommended by the Alliance for Aging Research
***Estimated Safe and Adequate Daily Dietary Intake

2. Should dietary supplements be subjected to the same regulations governing foods?

Food and dietary supplementation is such an important issue with regard to the health and safety of the general population that I believe that regulation can be carried out only at the federal government level. Currently manufacturers of dietary supplements need no Food Drug and Administration(FDA) evaluation or approval of their product. Under current law, manufacturers are not required to present evidence of product purity(or even demonstrate that the advertised ingredient is a legitimate part of the product)[11]. For now, FDA may only act against supplements that have been cited in consumer complaints. It is noted that in extreme cases, someone may have to die before FDA can remove the offending product from store shelves[3].

Fortunately, according to the document of Dietary

Supplements Health and Education Act(DSHEA) of 1994, FDA has proposed to amend current nutrient and health claim regulations and to change the terminology of dietary supplements and to provide the percentage level of dietary ingredients[12]. Nutrient claims regarding fat, saturated fat, cholesterol, and sodium, if there are any, would be required.

The regulations for labeling of certain ingredients in dietary supplements have already been revised. FDA has amended the existing regulation to establish Reference Daily Intakes(RDIs) for vitamin K, selenium, manganese, chromium, molybdenum, and chloride, but not for fluoride. The effective date of RDI establishment is Jan, 1997[1][13]. The agency has amended its regulations to modify the units of measure that are used to declare the amount of biotin, folate, calcium, and phosphorus in food.

In 1990, FDA proposed to amend food label reference values to replace the US RDA with RDIs for proteins and 26 vitamins and minerals[14]. The nutrients that were required to be labeled on conventional foods under the act described above were incorporated into RDIs regulation and appeared on food labels as Daily Values(DVs).

The agency has proposed to amend its nutrient content claim rule on the calorie content of foods or dietary supplements to allow sugar-free and no-sugar claims on supplements that meet the standards to make these claims[15]. The agency has also proposed to define the term high potency as a product that contains 100% or more of the RDIs for vitamins or minerals(or DV in the case of protein or fiber) for at least two thirds of the nutrients present and may be used only on supplements. The proposed rules would also provide a definition of the term antioxidant nutrient content claims in labeling of supplements and conventional foods.

Under the new regulations, most dietary supplements, regardless of their form, would be required to bear nutrition labeling that conforms to the general requirements and appears under the heading of Supplement Facts[1][16]. The heading of Amount per Serving will be used, except where the serving size of the product is one unit, and will appear over the column of amounts. FDA has proposed that the supplement fact panel list the dietary ingredients for which RDIs and DVs have been established, followed by a separate listing for those for which no such standards currently exist. In addition, the regulations also propose to require calories from the sub-components of nutrients and their health claims. It also requires the listing of non-required vitamins and minerals only when added for supplementation or when a claim is made. However, it has not required the listing of amounts of less than 2% of the RDIs for vitamins and minerals.

The proposed guidelines are expected to establish how best to provide truthful, scientifically valid, and non-misleading information to consumers so that they can make informed health care choices for themselves and their families[1][14]. They would also include recommendations for minimum and maximum dosages, approved and prohibited ingredients, and guidelines for claims that could be used on the labels.

While the importance of FDA vigilance is self evident, there is always the opposite risk of over-regulation. It would be unfortunate if desirable supplements were excluded from the marketplace due to unreasonable burdens of cost and procedural complexity.

If dietary supplements were to be subject to the rigorous scrutiny that the FDA requires for its pharmaceuticals, then their safety and efficacy would be assured. Full compliance may be unrealistic, however, given the current expense both in terms of time and finance to bring new drugs to market. It seems to me that there should be a balanced medium, neither proactive nor reactive toward dietary supplements.

3. What information would be necessary before health claims may be associated with a dietary supplement?

Proofs of health claims made by dietary supplements are only as good as faith in the integrity of the organization which judges them. As expressed earlier, this is why I believe that the FDA is the only body capable of claim substantiation. Claims offered by manufacturers may use sophisticated statistical approaches in an attempt to present us with relative risk interpretations of clinical trial data, and meta analyses interpretations of data collections[6]. Unfortunately, there is often no such a simple cause-effect relationship for diseases such as cardiovascular disease, cancer, stroke,

and diabetes.

Supplement use is more likely and more intense among individuals with one or more chronic health problems, suggesting the supplement use may be inspired by concerns about chronic health conditions[4]. Although consumers generally consider supplement use to be a health behavior, there is relatively little information about the relationship between health status and supplement use.

We do not know then whether most of these manufacturers' suggestive data is practically important to people over the long run as they eat good or bad diets, smoke or refrain from smoking, live in polluted or clean environments, and are either exercisers or couch non-exercisers. Until dietary supplements are subject to the same stringent regulations as prescriptive pharmaceuticals, consumers are left on their own to research the pros and cons of supplements so as to choose moderate-dose, well-balanced supplements and avoid poorly made, deceptively labeled, or unsafe ones[7].

If dietary supplements were regulated according to the same standards as are drugs, then it would be mandated to prove their efficacy and safety. The normal study procedures start out with animal trials which are then followed by limited human trials. Only then can they be tested by trials on a wide scale, which could be categorized into phases[17].

Each dietary supplement has its own safety profile, which must be clearly communicated to health professionals, and the lay public. Dissemination of accurate, scientifically based supplement safety information can result in the prevention of avoidable adverse effects.

In terms of choosing dietary supplements, some guidelines are available[7,9]. 1) Choose a multiple vitamin and mineral supplement, rather than several single supplements, 2) The supplement should provide no more than 300 percent of the RDA for all of the vitamins and mineral listed, 3) Natural dietary supplements are better than synthetic ones, because the former contain unidentified factors said to enhance nutrient utilization. The assumption may be made that these factors exist and were present in the raw material although whether they survive the extensive processing is not completely known.

Conclusion

It is necessary to realistically consider the data from recent major consensus documents and adopt a recommendation that avoids harm, yet provides benefits. It must come from a careful evaluation by the individual, perhaps with additional input from his or her health professionals, as long as they have thoughtfully evaluated the published data rather than simply accepting the pronouncements or recommendations of various political, scientific, and professional groups. The most important thing is to educate people to be more familiar with the information on nutritional labels of foods or dietary supplements in order to be knowledgeable regarding the importance of a balanced diet.

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