Matten, Ellen

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From: Crane, Nancy T [Nancy.Crane@cfsan.fda.gov]
Sent: Thursday, August 08, 2002 2:06 PM
To: Matten, Ellen
Subject: FW: FW: U.S. Draft Positions for Discussion Purposes at the 7-30-02 Codex Pu...

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Bill Sardi

For CCNFSDU public docket.

-----Original Message-----
From: BSardi@aol.com [mailto:BSardi@aol.com]
Sent: Thursday, August 08, 2002 1:32 PM
To: Crane, Nancy T
Subject: Re: FW: U.S. Draft Positions for Discussion Purposes at the 7-30-02 Codex Pu...

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August 8, 2002

U.S. Delegation to the CODEX Convention
Elizabeth Yetley, PhD
C/O Nancy Crane
Submitted by electronic transmission

Re: OBJECTIONS TO U.S. DRAFT POSITIONS (JULY, 2002)
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

While I have already written a letter to the U.S. CODEX delegation expressing my concerns over the establishment of upper limits for nutrients in food supplements, I have just obtained a copy of the Draft Positions of the U.S. Codex delegation and wish to make additional open comment on them.

The U.S. delegation to CODEX is commissioned to develop draft positions regarding vitamin and mineral supplements. While the Draft document addresses other topics, I confine my comment to vitamin and mineral supplements defined as "sources in concentrated forms of those nutrients alone or in combinations, marketed in capsules, tablets, powders, solutions, etc., not in conventional food form."

The U.S. draft position states that "The United States supports consumer choice and access to dietary supplements that are safe and are labeled in a truthful and non-misleading manner." The undefined term here is "safe." No explanation is given for the meaning of safe. Does this refer to morbidity and mortality? Does this include trivial or passing symptoms which occur from time to time with almost any medicine or supplement, such as nausea, transient diarrhea, headache, etc.? Will the consumer be able to distinguish minor or transient side effects from lethal or irreversible effects (i.e. liver toxicity). Since any substance can produce undesirable side effects if taken in a large enough dose (water, salt, spices, etc.), there is no such thing as absolute safety. So the CODEX guideline needs to be more specific and address "relative safety."

As previously stated, food supplements are safer than chlorinated tap water, acetaminophen, aspirin and ibuprofen, iron-fortified cereals, aspartame sweetener, and cow's milk, all which are sold over-the-counter without a statement regarding upper safe limits.

As has been stated in previous communication with the U.S. CODEX delegation, there is an assumption that there is a problem that needs to be fixed.

Exactly what are the documented side effects of food supplements consumed in high doses and what is their incidence in the general population? Is CODEX protecting two percent of the mega-dose vitamin E users from headaches, or what? Would the establishment of an "upper limit" be expected to eliminate or just reduce the Occurrence of side effects?

The CODEX Draft notes that the Codex Guidelines for Vitamin and Mineral Supplements will not, in any way, adversely affect the availability of safe and truthfully labeled supplement products in the U.S. marketplace or to U.S. consumers. While this sentence is encouraging to consumers of food supplements, it is incomplete. There are other concerns regarding the effect of CODEX.

The very establishment of upper limits on food supplements would likely scare away consumers from these products at a time when conventional medicine is beginning to warm up to the idea of the value of food supplements for health promotion. The first press releases issued upon the establishment of upper limits are likely to create a mistaken belief that food supplements are relatively unsafe. Consumers are likely to assume that since, let's say 2000 milligrams of vitamin C is the upper safe limit, that 2000 milligrams is the toxic level and they should consume far less so as to never experience side effects. In fact, if 2000 milligrams were established as a relatively safe upper limit, it would likely have a safety margin built into it. Exceeding the upper limit may produce no side effects whatsoever in a majority of consumers. The consumer will probably not be told that the upper limit is the lower threshold for side effects. I have observed adults who have never taken vitamin C supplements experience diarrhea at doses as low as 500 milligrams.

The CODEX Draft states "Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer should take the following criteria into account: (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups." Just how would CODEX address the variable nutritional needs of humans of mixed genetic and environmental backgrounds? Excessive folic acid may mask a vitamin B12 deficiency, but fertile women who seek motherhood need extra folic acid (some experts say up to 2000 mcg) to reduce the risk of birth defects in their offspring. So is the caveat to be aware of a masked B12 deficiency to be discarded for women who take mega-dose folic acid? An upper limit of 2000 IU for vitamin D has been proposed. How would that accommodate blacks living in northern climates (near the Canadian border) whose skin pigmentation reduces the production of vitamin D from sunlight?

Self care of illness and disease may be inappropriately discouraged by the establishment of a safe upper limit. While self care is not likely to be promoted by any health professionals, frankly many consumers have no health insurance or suffer with disorders for which conventional medicine has no answers. The fact is that informed consumers who seek alternatives to the physician-promoted pharmaceutical drugs may not be able to obtain food supplements in convenient or cost-effective doses for the self care of disease if upper safe limits are established. For reasons of liability, manufacturers of food supplements are likely to steer clear of providing vitamins and minerals in doses that exceed the upper limit. Thus consumers who wish or need to consume food supplements in mega doses may experience increased costs to obtain nutrients in small-dose pills. The products would be available, but just not convenient nor affordable.

The CODEX Draft states: "Supplements of some nutrients, such as vitamin A and selenium, can be harmful if taken in large amounts." This statement is again misleading if not a falsehood. Vitamin A is potentially toxic to the liver, but this problem only occurs in about 30 to 40 cases a year while millions of Americans are believed to be deficient in vitamin A. Selenium is potentially toxic, but selenium poisoning has only occurred in artificial circumstances such as when strip mining exposed mineral beds and increased elemental mineral levels in drinking water. Organically-bound selenium provided in plant foods (i.e. garlic) has never been demonstrated to be toxic regardless of dose. CODEX advocates science-based review of supplements but offers examples which are inaccurate and disparaging.

The CODEX Draft states that "Some people need a vitamin-mineral supplement to meet specific nutrient needs." This sentence needs to be changed to "most if not all people at some stage of their life will need vitamin-mineral supplements to meet specific nutrient needs."

Growing children would be less healthy if we did not already fortify our overly-processed foods. All childbearing women require supplemental nutrition. All older adults are at greater risk for age-related disease and malabsorption and should supplement their diet. All full-grown males need to chelate iron from their system to avoid iron overload. Recent studies indicate 40% of Americans are deficient in vitamin D, 40% short on vitamin B12, 80% deficient in magnesium, 80% deficient in essential fatty acids and the entire human population suffers from a genetic failure to produce an enzyme that naturally produces vitamin C.

How can it be said in the CODEX Draft that "Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement. In cases where the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral supplements serve to supplement the daily diet"? This statement is out of date and patently untrue. Even the American Medical Association has now published reports which advocate multivitamin usage for the population at large. This is further evidence that CODEX is currently out of step with a rapidly changing body of nutritional science.

The CODEX Draft says: "The absence of science-based Codex guidelines, however, could adversely affect the ability of U.S manufacturers to compete in the international marketplace." How so? This sentence goes unexplained. There are no CODEX guidelines in force today and manufacturers are not impeded from entering the international marketplace. Is this another non-problem in search of a fix? Please explain.

Are we to assume that if an upper safe limit is established by the world community, and U.S. CODEX does not agree, that U.S. manufacturers would be at some disadvantage? All U.S. manufacturers need do is reduce the dosage in their products to comply with foreign requirements, which is hardly much of an inconvenience. This would likely result in higher dose U.S. products being coveted by the overseas market. This is the case today where Canada and various European countries limit the types or dosage of food supplements. Foreign travelers in the USA often purchase loads of food supplements to bring home. The US.-made products are coveted, not rejected b consumers. It is only the foreign governments, largely influenced by p armaceutical interests, which inhibit a free market.

The CODEX Draft states: "In the spirit of the protection of international fair trade practices and the science-based resolution of international trade disputes, we support the development of CODEX guidelines for vitamin and mineral supplements that do not unduly limit consumer access to safe and truthfully labeled dietary supplement products." It becomes clear here that CODEX addresses commercial interests over that of consumer needs. This sentence does not indicate consumer needs supercede those of commercial interests.

The CODEX Draft states: "The selection of vitamin and mineral sources should be based upon considerations such as safety and bioavailability." This sentence again requires further explanation. According to the Food & Drug Administration, food supplement manufacturers are prohibited from making statements that their products are safe or effective. Are consumers to assume nutritional supplements are relatively safe if taken in lower doses, or toxic if taken in higher doses? Furthermore, there is no current requirement for nutritional products to list "bioavailability" on their label. How would a consumer understand "bioavailability?"

The CODEX Draft states that "The minimum level of each vitamin and/or mineral in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should be 15 percent of the recommended daily intake as determined by FAO/WHO." Otherwise the supplement will not

be considered a significant source of a particular nutrient. To amplify the above statement, the CODEX Draft goes on to say: "Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer should take the following criteria into account â?¡the daily intake of vitamins and minerals from other dietary sources." This statement requires additional explanation. The problem here is that the recommended daily intake is comprised of the amount obtained from the diet and supplements. For example, the recommended daily consumption of calcium is 1200 milligrams for adults. The dairy-rich American diet provides approximately 800 milligrams of calcium on average with a significant portion of the population already consuming sufficient amounts (1200 mg+) of calcium from the diet.

Ten percent of the daily calcium requirement, or 120 milligrams, would not be considered a significant amount under the proposed guideline of 15% of the daily requirement. However, the difference between the average daily consumption, 800 milligrams, and the recommended intake, 1200 milligrams, is only about 400 milligrams. The 400 milligram gap would be the suggested amount for dietary supplementation. The consumption of 120 milligrams of supplemental calcium would make up for 30 percent of the shortage between 800 and 1200 milligrams. Thus 120 milligrams of calcium in this example would provide a significant amount of this mineral. Just 60 milligrams of calcium would meet the 15 percent requirement outlined in the CODEX draft.

The CODEX Draft states that "All labels should bear a statement that the supplement should be taken on the advice of a nutritionist, a dietician or a medical doctor." Is this provision going to result in sanctions against any untrained person who recommends a nutritional supplement to a family member or friend? In some other countries there is restriction of free speech as the public faces certain sanctions if they speak out on the health benefits of food supplements. Does CODEX promote a guideline that suggests only the elite-class of trained nutritionists can offer advice on the use of food supplements? Would this CODEX provision inhibit or prohibit answers to consumer question by safes clerks at health food stores?

The CODEX Draft states: "The label should contain a warning statement, if the product contains an amount of a nutrient that has been shown through science-based risk assessment to be a health hazard under conditions of use." Does this mean that any product that provides an amount of a nutrient that exceeds the safe upper limit will now have to carry a warning statement? What if the nutrient poses potential hazards within the established safe range? For example, take iron. Iron is a potentially toxic supplemental nutrient for full-grown males. It accumulates in males beginning at the age of physical maturation (about age 18) at about 1 milligram per day of life and worsens all forms of infection and disease and leads to the early demise of males compared to females. Supplemental iron, provided in a "safe dosage range" could still be considered to be problematic. It is unlikely there will be sufficient space on the product label to include such a lengthy explanation.

The CODEX Draft states: "These guidelines are intended to ensure a high level of protection and to facilitate informed choice for consumers of vitamin and mineral supplements." The misinformation and non-specific guidelines in the CODEX Draft provide contrary evidence to the above statement. Under the guise of protection, food supplements in certain doses will be branded as toxic when this is far from fact. The misinformation and lack of knowledge displayed in the CODEX Draft of July, 2002 is enough to call for the resignation and replacement of the current U.S. delegate to CODEX and a revision of the members of the CODEX delegation to include parties who are more up to date in their knowledge of this important subject.

Sincerely,

Bill Sardi