A Compilation of Dietary Supplement Statements

From the Scientific Report of the 2015 Dietary Guidelines Advisory Committee



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For your convenience, the NIH Office of Dietary Supplements has compiled in this document statements in the 2015 Dietary Guidelines Advisory Committee (DGAC) Report that pertain or are related to the subject of dietary supplements. Each statement refers to the page and line where it appears in the full DGAC report (see <u>PDF version</u>).

Transmittal letter to Secretaries of DHHS and USDA

(Page 1) Under-consumption of vitamin D, calcium, potassium, and fiber are of public health concern for the majority of the U.S. population.

Part A: Executive Summary

(Page 2, line 48) The DGAC found that several nutrients are underconsumed relative to the Estimated Average Requirement [EAR] or Adequate Intake [AI] levels set by the Institute of Medicine (IOM) and the Committee characterized these as shortfall nutrients: vitamin A, vitamin D, vitamin E, vitamin C, folate, calcium, magnesium, fiber, and potassium. For adolescent and premenopausal females, iron is also a shortfall nutrient. Of the shortfall nutrients, calcium, vitamin D, fiber, and potassium also are classified as nutrients of public health concern because their underconsumption has been linked in the scientific literature to adverse health outcomes. Iron is included as a shortfall nutrient of public health concern for adolescent females and adult females who are premenopausal due to the increased risk of iron-deficiency in these groups.

Part B. Chapter 1: Introduction

(Page 13) The area of "Healthy Nutritional Status" in the model includes the topic of "Dietary product and nutrient supplement use."

Part B. Chapter 2: Themes and Recommendations: Integrating the Evidence

(Page 1, line 28) Underconsumption of the essential nutrients vitamin D, calcium, potassium, and fiber are public health concerns for the majority of the U.S. population, and iron intake is of concern among adolescents and premenopausal females.

(Page 6, line 189) The 2015 DGAC advocates achieving healthy dietary patterns through healthy food and beverage choices rather than with nutrient or dietary supplements except as needed.

Part D. Chapter 1: Food and Nutrient Intakes, and Health: Current Status and Trends (Page 1, line 11) Notably, the DGAC considers that the primary source of nutrients should come from foods and beverages. Nutrient-dense forms of foods (those providing substantial amounts of vitamins, minerals and other nutrients and relatively few calories) are recommended to ensure optimal nutrient intake without exceeding calorie intake or reaching excess or potentially toxic levels of certain nutrients.

(Page 1, line 27) The 2015 DGAC did not specifically address multivitamins, but recognizes that some dietary supplements may be recommended for some populations or life-cycle phases (pregnancy, for example).

(Page 9, line 322) To determine nutritional adequacy, the DGAC used 2007-2010 NHANES/WWEIA [National Health and Nutrition Examination Survey/What We Eat in America] data to examine the intake distributions for 11 vitamins (vitamin A, vitamin B_6 , vitamin B₁₂, vitamin C, vitamin D, vitamin E, vitamin K, folate, thiamin, niacin, and riboflavin), nine minerals (calcium, copper, iron, magnesium, phosphorous, potassium, selenium, sodium, and zinc), energy, macronutrients (total fat, saturated fat, polyunsaturated fat [including 18:2 and 18:3], protein, carbohydrate), and other compounds or components (fiber, carotenoids [alpha-carotene, beta-carotene, lycopene, lutein + zeaxanthin], caffeine, cholesterol, and choline) (see Appendix E-2.1: Usual intake distributions, 2007-2010, by age/sex groups). The DGAC compared the intake estimates across the population age distribution to the Dietary Reference Intakes. The committee used data from foods and beverages as well as foods and beverages plus dietary supplements when supplement data were available. For nutrients with an EAR, the DGAC considered shortfall nutrients to be those where a substantial proportion of either the total population or specific age and sex subgroups had intake estimates below the EAR. Although multiple approaches can be used to estimate the prevalence of nutrient inadequacy in a population, the DGAC used the EAR cut point method. Figure D1.1 shows the percent of the U.S. population with usual intakes below the EAR. From Figure D1.1, the DGAC determined that vitamin D, vitamin E, magnesium, calcium, vitamin A and vitamin C were shortfall nutrients and that there may be a high prevalence of inadequate dietary intake of these nutrients.

Of the nutrients with an AI (vitamin K, choline, dietary fiber, and potassium), the DGAC determined that a low proportion of the population had fiber and potassium intakes above the AI and so potassium and fiber were therefore considered to be underconsumed (Figure D1.2).

(Page 10, line 358) In addition to the age groups shown in Figures D1.1 and D1.2, the DGAC was interested in understanding the intake of shortfall nutrients in older adults (71 to 79 years and 80 years and older). Calcium intake from foods and beverages did not meet the EAR for older persons, where 71 percent of males and 81 percent of females

ages 71 years and older had intakes below the EAR. For these analyses calcium from dietary supplements was also considered. When total intake of foods + beverage + dietary supplements containing calcium was considered, then the proportion of the older adults below the EAR improved to 55 percent for men and 49 percent for women over the age of 71 years. For vitamin D intakes from food and beverages only, about 93 percent of older males and more than 97 percent of older females had intakes below the EAR. Similar to the findings for calcium, intakes improved when considering total intake from foods and beverages plus dietary supplements. The proportions of older adult below the EAR dropped to 52 percent for both males and females older than 71 years.

(Page 10, line 372) Potassium also was a shortfall nutrient for both older males and females, where less than 3 percent of both groups had intakes above the AI. Use of dietary supplements containing potassium did not change the proportion of the older adults with intakes above the AI.

(Page 13, line 473) Nutrient intake data, together with nutritional biomarker and health outcomes data indicate that vitamin D, calcium, potassium, and fiber are underconsumed and may pose a public health concern. Iron also is a nutrient of public health concern for adolescent and premenopausal females.

(Page 15, line 537) [Focus on vitamin D.] ...multiple national and international groups, including the American Academy of Pediatrics (AAP), the Endocrine Society and the National Osteoporosis Foundation have recommended that strategies to achieve the RDA [Recommended Dietary Allowance] or higher levels of vitamin D intake could include consumption of fortified foods, broadening the range of dairy products that are fortified, and consideration, in some cases, of the use of a vitamin D supplement or a multivitamin including vitamin D. Such a use is especially appropriate where sunshine exposure is more limited due to climate or sunblock use.

(Page 15, line 562) [Focus on calcium.] Strategies to improve calcium intake include increased dairy or fortified products that are important sources of calcium. Concern about the safety of calcium supplements and a relative lack of data about the health benefits of such supplements limit recommendations to use supplementation as a strategy to meet the RDA for calcium, compared to using fortified foods.

Question 3: Is there evidence of overconsumption of any micronutrients from consumption of fortified foods and supplements?

• (Page 18, line 664) Dietary patterns among Americans, including typical use of fortified foods, rarely lead to overconsumption of folate, calcium, iron, or vitamin D. However, each of these nutrients, as well as other nutrients, are overconsumed in <u>some</u> supplement users, especially those taking high-dose supplements.

- (Page 18, line 670) The public may safely use dietary supplements containing RDA level of nutrients, so long as total intake from diet plus supplements does not exceed the UL [Tolerable Upper Intake Level]. Use of products with high doses of nutrients, such that total intake exceeds the UL, should be discussed with a Registered Dietitian or other qualified health care provider.
- (Page 18, line 675) Supplement users should seek guidance about factors such as whether the amount of nutrients in supplements exceeds the UL for those nutrients. Monitoring of dietary patterns in supplement users should continue to be done, with attention paid to the highest risk groups, such as children and women who are pregnant.
- (Page 19, line 691) **Folate.** The use of supplemental folic acid exceeds the established UL in a small proportion of children, especially those younger than age 9 years. However, this UL is not based on clinical toxicity data in this population and exceeding the UL is primarily associated with supplement use. The risk associated with usual folate intakes among children in the United States is considered low, but caution should be used in advising supplements for children younger than age 9 years.
- (Page 19, line 697) **Calcium.** Dietary calcium intake greater than 2000 mg/day (UL) are seen in up to about 20 percent of females, and 15 percent of adult males older than age 50 years. These high intakes are driven primarily by a historical perspective that very high calcium supplement usage may decrease the risk of osteoporosis. Concern exists about the safety of such high intakes and the possible association with CVD [cardiovascular disease] risk and little, if any, current evidence supports intakes of calcium above the UL for the purpose of decreasing osteoporosis. Of note, the World Health Organization recommends high dose calcium supplementation (1.5-2 g/day) to prevent hypertensive disorders of pregnancy. This recommendation is not widely followed among low-risk women in the United States. However, use of calcium supplements does not appear to pose a health risk related to overconsumption of calcium.
- (Page 19, line 707) **Iron.** In adults of all ages, a small proportion of iron supplement users have intakes above the UL. Concerns related both to cardiovascular health and oxidant damage exist, but are not well-defined. Iron supplementation is very common during early childhood and pregnancy, but is unlikely to pose a health risk.
- (Page 19, line 712) **Vitamin D.** Overconsumption of vitamin D occurs when individuals take high dose supplements, usually over a long period of time. The UL of 4000 IU/day is commonly exceeded by individuals with or without the guidance of a physician. In general, it is unlikely that most supplement users, who limit themselves to 10,000 IU/day or less, will have any evidence of toxicity, but a greater risk may exist among some groups, including small children. Those who

take high dose supplements often have their serum/plasma 25-hydroxyvitamin D concentrations monitored and this can be helpful although no clearly toxic level of 25-hydroxyvitamin D in the blood is known. Overall, the population risk of overconsumption of vitamin D leading to toxic effects, including hypercalcemia or other clinical symptoms, is uncommon.

(Page 21, line 790) ...potassium and vitamin D intakes require assessment both of individual intake and population intake patterns of foods or supplements to ensure that needs for physiological functioning are met. Meeting the needs for these nutrients may require careful attention to excellent natural sources, food enriched or fortified with the nutrients, or, in some cases, consideration of supplements.

(Page 22, line 800) In some situations, specific foods or dietary supplements may be used to increase underconsumed nutrient intakes not met through the USDA Food Patterns.

(Page 24, line 905) Through the use of a diet rich in seafood and fortified foods, EAR, but not RDA, levels of vitamin D can be achieved. Additional fortification or supplementation strategies would be needed to reach RDA levels of vitamin D intake consistently, especially in individuals with low intakes of fish/seafood or fortified dairy foods, other fortified foods (e.g. breakfast cereals) and beverages.

(Page 25, line 911) Diet is an important aspect of achieving vitamin D intake targets. The U.S. population should be encouraged to choose foods and beverages fortified with vitamin D. When needed, supplementation can be considered to achieve RDA intakes of vitamin D.

(Page 25, line 917) It may be difficult for individuals to reach the RDA intake of vitamin D from food, including food as it is currently fortified in the United States. ... Vitamin D exposure, and likely status, is assessed generally through serum/plasma 25hydroxyvitamin D concentrations. However, this test is not recommended for routine screening of the entire population due to costs and challenges in obtaining measurements throughout the year and interpreting results in populations, including those who are obese. Because many non-screened individuals will still need to reach the RDA for vitamin D, supplement use may be considered for this purpose.

Needs for future research:

• (Pages 77, line 2874) 5. Evaluate the effects of common variations in dietary patterns in small children on nutrient intakes. **Rationale:** Children from 2 to 4 years of age have a highly variable diet and often do not fit readily into the USDA Food Pattern food groups diet pattern analyses. Further information is needed to

understand the broad range of diets and supplement use in small children and how this relates to nutrient intake and growth.

- (Page 78, line 2897) 8. Evaluate effects of fortification strategies and supplement use on consumer behavior related to the intake of foods and supplements containing key nutrients, including calcium, vitamin D, potassium, iron, and fiber. Rationale: The intake of key nutrients of concern is considerably affected by the rapidly evolving marketplace of food fortification and supplementation. Understanding consumer behavior related to fortification and supplementation would be important in predicting the effects of interventions and marketplace changes in content of these nutrients. Special interest exists regarding fortification strategies of foods, including whole grains and yogurts, in allowing individuals to reach the RDA for vitamin D without using supplements. Data are needed on how supplements may help meet nutrients shortfalls and/or how use of supplements may place individuals at risk of overconsumption. Research on effective consumer guidance is needed.
- (Page 78, line 2909) 9. Understand the rationale for and consequences of the use of supplements above the UL for vitamins and minerals. Identify biochemical markers that would indicate the effects of high-dose supplement use. **Rationale:** Consumer use of high-dose supplements has increased. Understanding the influences guiding this use would be helpful in considering how to educate consumers about safe upper intake limits.

(Page 133) Figure D1.5 Supplement users: Percent with usual intakes [of iron, calcium, vitamin D, and folic acid] from foods, beverages, and supplements greater than the UL.

Part D. Chapter 5: Food Sustainability and Safety

(Page 33, line 1200) The main sources of caffeine among both adults and children are coffee, tea, and carbonated soft drinks. Another product, which has received a lot of attention recently as a potential source of excessive caffeine intake, especially among younger populations, is energy drinks. An energy drink is a beverage that contains caffeine as its active ingredient, along with other ingredients such as taurine, herbal supplements, vitamins, and sugar. It is usually marketed as a product that can improve energy, stamina, athletic performance, or concentration. Energy drinks are relatively new to the market and have evaded oversight and regulation by the FDA due to their classification as dietary supplements, or because their components are generally recognized as safe.

(Page 50, line 1744) Limited or no consumption of high caffeine drinks, or other products with high amounts of caffeine, is advised for children and adolescents. Energy drinks with high levels of caffeine and alcoholic beverages should not be consumed together, either mixed together or consumed at the same sitting.

Needs for future research

(Page 53, line 1852) 13. Define excessive caffeine intake and safe levels of consumption for children, adolescents, and young adults. **Rationale:** Current research on caffeine and health outcomes has focused primarily on adults. Given the increasing prevalence of energy drink consumption among children, adolescents, and young adults, research is needed to identify safe levels of consumption in these groups.