February 3, 2014

The Council for Responsible Nutrition (CRN) appreciates the opportunity to provide comments regarding the development of the 2015 Dietary Guidelines for Americans. CRN respectfully requests that the DGAC consider the following questions that can be addressed through an evidence-based review:

- 1. Is taking a calcium and vitamin D supplement an effective way to achieve nutrient adequacy within calorie limits when nutrient intake is not first met through food?
- 2. Does a calcium and vitamin D supplement help support bone health in certain populations?

The 2010 DGAC identified calcium and vitamin D as nutrients of public health concern due to insufficient intake (1). Government research demonstrates that many Americans continue to fall short of their nutrient requirements for calcium and vitamin D when consumed from food and beverages, including fortified foods (2,3,4). According to NHANES 2007-2010 data, 42% and 94% of Americans 1 year of age and older consume calcium and vitamin D at levels below their respective EARs (4). Therefore, both calcium and vitamin D remain nutrients of concern and the use of dietary supplements could help individuals achieve adequacy for these nutrients (2,3,5). Of note, the prevalence of calcium insufficiency in women 19 years and older identified as supplement users in NHANES 2003-2006 substantially declined from 61% to 24% when intake of calcium supplements was included in calcium intake from food sources (3). More recent data from NHANES 2009-2010 also show that consumption of calcium supplements helps Americans reach adequacy, specifically males ages 60 and older and females ages 20 and older (5). Furthermore, measures of vitamin D status show that about one-quarter of the US population are at risk of vitamin D inadequacy, and 8% are at risk of vitamin D deficiency (6).

Evidence does not indicate overconsumption of calcium and vitamin D from the use of supplements, with only 2.4% and 0.1% of Americans 2 years and older exceeding the ULs for calcium and vitamin D, respectively, when taking into account intakes from foods and supplements (2). Intakes of calcium above the UL remains low (6%) even when the population group only includes adult supplement users (3).

Beyond their demonstrated function in helping Americans achieve nutrient adequacy, calcium and vitamin D supplements have been shown to support bone health, particularly in postmenopausal women. A recent re-analysis of the Women's Health Initiative (WHI) clinical trial data indicated a reduction in the risk of hip fracture in post-menopausal women who received calcium and vitamin D supplements for at least 5 years compared to placebo, specifically in a large subgroup of 15,302 women who reported no use of calcium and vitamin D supplements at baseline (7). This association was strengthened when the intervention data were combined with the WHI observational study data in the subgroup of 23,561 women with no baseline use of calcium and vitamin D supplements (7).

The re-analysis of the WHI study data also demonstrated no significant increase in the risk of myocardial infarction, coronary heart disease, total heart disease, stroke, total cardiovascular disease (CVD), or death, either in the overall study population of over 36,000 post-menopausal women or in the subset who did not use calcium and vitamin D supplements at baseline (7). These findings call into question earlier suggestions that calcium intake or supplementation may be associated with an increased risk of adverse cardiovascular outcomes. Additionally, a review of studies that served as the basis of the U.S. Preventive Services Task Force draft recommendations regarding the benefits and harms of vitamin and mineral supplementation for the prevention of cancer, CVD, and all-cause mortality concluded that the available data are insufficiently consistent to support the conclusion that supplementation with calcium is harmful (8). Similar conclusions were reached in a recent review of calcium supplement use and CVD risk (9). A systematic review also showed a 6% significant decreased risk of mortality with vitamin D supplementation (10).

Moreover, the benefits of calcium and vitamin D supplementation for bone health in postmenopausal women may be translated into health care cost savings. The annual direct health care cost of treating fractures in U.S. women over the age of 55 with osteoporosis was over \$14 billion in 2012 (11). If calcium and vitamin D supplements were used at preventive daily intake levels by all U.S. women over the age of 55 and diagnosed with osteoporosis, the net health care cost savings would average \$1.52 billion per year, with cumulative potential net savings of \$12.5 billion from 2013 to 2020 (11). Thus, the use of calcium and vitamin D supplements may help to reduce the financial burden of osteoporosis.

CRN thanks the DGAC for considering the aforementioned evidence-based review questions. As summarized herein, evidence supports an important role for calcium and vitamin D supplements in helping Americans achieve nutrient adequacy without added calories and contributing to bone health in certain populations.

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