

January 21, 2025

USPSTF Coordinator c/o USPSTF 540 Gaither Road Rockville, MD 20850

Re: Opportunity for Comment - U.S. Preventive Services Task Force Draft Recommendation Statement for Vitamin D, Calcium, or Combined Supplementation for the Primary Prevention of Falls and Fractures in Community-Dwelling Adults: Preventive Medication

The Council for Responsible Nutrition (CRN)¹ appreciates the opportunity to comment on the U.S. Preventive Services Task Force (USPSTF) Draft Recommendation Statement for Vitamin D, Calcium, or Combined Supplementation for the Primary Prevention of Falls and Fractures in Community-Dwelling Adults.

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

CRN has organized its comments according to the questions posed by the USPSTF in the USPSTF Public Comment Form.

Based on the evidence presented in this draft Recommendation Statement, do you believe that the USPSTF came to the right conclusions?

- a. Yes; I believe the USPSTF came to the right conclusions.
- b. Somewhat; I believe the USPSTF came to the right conslusions in some ways but not in others.
- c. No; I do not believe the USPSTF came to the right conclusions.
- d. Unsure; I am unsure if the USPSTF came to the right conclusions.

Please provide additional evidence or viewpoints that you think should have been considered.

As presented in CRN's comments on the USPSTF Draft Research Plan, we maintain that vitamin D status (indicated by serum concentrations of 25- hydroxyvitamin D [25(OH)D]) is a critical component of any research that is conducted to investigate the relationship between vitamin D and health outcomes. As such, vitamin D status should be considered in the studies comprising the evidence review.

Supplementation with a particular dose of vitamin D will not have the same impact across individuals in a population group. It may provide benefits to some individuals but may not have an effect in others, depending on the individual's vitamin D status at baseline, along with other factors (such as absorption, metabolism, and polymorphisms in key vitamin D dependent genes). Assessing fracture and fall risk, as well as other health outcomes (including potential harms) based on vitamin D dose in isolation does not provide meaningful information. Instead, vitamin D status, which may be altered by vitamin D supplementation, is a determinant of health outcomes.

CRN notes that several studies underpinning USPSTF's draft recommendations did not consider participants' baseline vitamin D levels. If participants in these studies had adequate vitamin D levels at the beginning of the study, increasing vitamin D levels via supplementation may not result in additional benefit. Conversely, increasing vitamin D levels in participants with insufficient levels as baseline could have an impact on fall and fracture risk.

As a result of the narrow research plan, CRN has concerns that the draft Recommendation Statement is severely limited, excluding a large portion of the population at risk for falls and fractures. The USPSTF's draft recommendations target community-dwelling postmenopausal women and men ages 60 years and older, and as outlined in the "Patient Population Under Consideration" section, "These recommendations do not apply to persons with a history of osteoporotic fractures, medical conditions associated with vitamin D deficiency or vitamin D malabsorption, or a diagnosis of osteoporosis or vitamin D deficiency."

Older adults with limited sun exposure, restricted diets, or darker skin tones often face a higher risk of vitamin D deficiency. Both vitamin D and calcium are consistently underconsumed by the U.S. population, with the Dietary Guidelines for Americans identifying them as nutrients of public health concern. The Scientific Report of the 2025 Dietary Guidelines Advisory Committee indicated that 89% of males and >97% of females 71 years of age and older have vitamin D intakes below the Estimated Average Requirement (EAR), while 58% of males and 82% of females 71 years of age and older have calcium intakes below the EAR. The draft recommendations exclude patient populations that are most at risk for falls and fractures and could benefit from supplemental vitamin D and calcium.

What resources or tools could the USPSTF provide that would make this Recommendation Statement more useful to you in its final form?

In the section, "Additional Information" under the tab, "Related Resources and Tools," the USPSTF provides a Patient Summary to the draft Recommendation Statement as a resource for clinicians and their patients. The Patient Summary explains the draft Recommendation Statement in consumer-friendly language and communicates the importance of vitamin D and calcium for overall health and the need for all people to get their daily allowance of these essential nutrients.

CRN believes that the narrow focus of the draft Recommendation Statement on the primary prevention of falls and fractures, if not clearly communicated, could lead to misinterpretation that the USPSTF warns against supplementation of calcium and vitamin D. To prevent misinformation, USPSTF should communicate the limited focus of its draft Recommendation Statement throughout the Patient

Summary. For example, under the section "What does the USPSTF recommend?", in response to the question "So, what does that mean?" CRN recommends the following statement: "Healthy older adults with sufficient vitamin D and calcium intake do not need to take vitamin D supplements, with or without calcium, as the primary way to prevent falls and fractures. However, 89 essential nutrients that are important for overall health and supplementation can help individuals achieve their recommended daily allowances. Older adults who have vitamin D deficiency, osteopenia, osteoporosis, or a medical condition affecting vitamin D and/or calcium absorption should speak to their healthcare provider about the need to supplement with vitamin D and calcium."

Moreover, the "Why is this draft recommendation and topic important" section should be modified so that the second bullet reads, "On their own, vitamin D and calcium supplements do not prevent falls and fractures in healthy individuals with sufficient levels of vitamin D and calcium. However, both nutrients are important for overall health, and it is important that everyone consumes the recommended daily allowance of these nutrients. In addition, the "What are the benefits" section should be revised to read, "In healthy older adults with sufficient levels of vitamin D and calcium, there is no additional benefit in taking vitamin D, with or without calcium, solely to prevent falls and fractures in older adults who are not taking these supplements for other specific medical reasons." CRN believes these modifications help patients to better understand the limited nature of the recommendation statement and avoid misinterpretation that calcium and vitamin D should be avoided altogether, which would be a detriment to health.

The USPSTF is committed to understanding the needs and perspectives of the public it serves. Please share any experiences that you think could further inform the USPSTF on this draft Recommendation Statement.

CRN has concerns that the draft Recommendation Statement excludes a significant portion of the population that is vulnerable to falls and fractures, particularly those with vitamin D deficiency. By not addressing the needs of these groups, the recommendations fail to help the broader public the USPSTF is intended to serve. Further, we recognize that misinterpretation of highly scientific statements by stakeholders, such as the media, disservices patients and consumers. We appreciate that USPSTF representatives made efforts to explain to reporters what the draft recommendation means and stress that calcium and vitamin D are essential for overall health, and it is important to ensure intake of recommended daily amounts. We emphasize that the latter point needs to be made clear across all communications related to the Recommendation Statement, including resources for clinicians and patients.

CRN Comments on USPSTF Draft Recommendation Statement for Vitamin D, Calcium, or Combined Supplementation for the Primary Prevention of Falls and Fractures in Community-Dwelling Adults January 21, 2025

Respectfully Submitted,

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Council for Responsible Nutrition