

Submitted electronically via taylor.wallace@nof.org

June 21, 2016

Taylor Wallace, Ph.D.
National Osteoporosis Foundation
251 18th Street S, Suite 630
Arlington, VA, 22202

Dear Dr. Wallace,

The Consumer Healthcare Products Association (CHPA)¹ appreciates the opportunity to provide the National Osteoporosis Foundation (NOF) with comments on their recently released ‘*Position Statement on Calcium and Cardiovascular Disease*’ as well as the Evidence Report on which it is based. Several of our member companies market calcium-containing dietary supplement products and as such we have an interest in ensuring consumers are provided with accurate, up to date information concerning the safe use of calcium containing supplements as a means of supporting a healthy lifestyle.

The public health need for adequate calcium intake

Calcium is the most abundant mineral in the body and is required for building bones and teeth, blood vessel health, muscle function, nerve transmission, intracellular signaling and hormone secretion. Despite its critical role in many physiologic processes, calcium intake among the U.S. population continues to be low as shown by results from the National Health and Nutrition Examination Survey (NHANES) demonstrating that 42% of Americans are falling below suggested intake values.² Calcium and Vitamin D have also been identified in the recently released Dietary Guidelines as nutrients of public health concern (due to under-consumption).³ Low calcium intake has been associated with an increased risk for osteoporosis, bone fractures

¹ CHPA is the 135-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products (chpa.org).

² [U.S. Department of Agriculture, Calcium Intake of the U.S. population, What We Eat in America, NHANES 2009-2010](#); September 2014

³ [Dietary Guidelines for Americans 2015-2020, 8th Edition](#)

and falls. Recent estimates suggest that more than 50 million Americans over 50 years of age have osteoporosis or low bone mass.⁴ Observational study results⁵ and a recent meta-analysis⁶ suggest that calcium and Vitamin D supplementation can reduce fracture incidence in some middle-aged to older adults.

- **Use of dietary supplements helps consumers address dietary calcium inadequacies**

A number of good dietary sources of calcium are available including dairy products, sardines, fortified juice, green leafy vegetables and soy products.⁷ While eating a variety of nutrient-dense foods is generally the best way to obtain sufficient intake of key vitamins and minerals (including calcium), supplementation remains an excellent way to compensate for nutritional shortfalls. Indeed, research shows that a significant percentage of U.S. adults take some form of dietary supplement in order to support a healthy lifestyle.^{8,9} The average recommended daily intake of calcium changes throughout the life-cycle and many people do not get adequate calcium from their diet. Responsible use of calcium-containing dietary supplements helps those who cannot get enough calcium from their diet to maintain adequate levels.

- **Importance of the NOF Report - conflicting science**

Although findings from a recent meta-analysis¹⁰ as well as a clinical trial¹¹ have contributed to concern about a possible association between use of calcium supplements and a small increase in

⁴ Wright *et al.*, 2014 The recent prevalence of osteoporosis and low bone mass in the United States based on bone mineral density at the femoral neck or lumbar spine *J Bone Miner Res* 29(11): 2520-6

⁵ Weaver *et al.*, 2016 Calcium plus vitamin D supplementation and risk of fractures: an updated meta-analysis from the National Osteoporosis Foundation *Osteoporosis Int* 27(1): 367-76

⁶ Prentice *et al.*, 2013 Health risks and benefits from calcium and vitamin D supplementation: Women's Health Initiative clinical trial and cohort study *Osteoporosis Int* 24(2): 567-80

⁷ See Table A11-1 "Calcium: Food Sources Ranked by Amounts of Calcium & Energy per Standard Food Portions & per 100 Grams of Foods" from [Dietary Guidelines for Americans 2015-2020, 8th Edition](#)

⁸ Bailey *et al.*, 2010 Estimation of total usual calcium and vitamin D intakes in the United States, *J Nutrition* 140(4): 817-22.

⁹ Bailey *et al.*, 2013 Why US adults use dietary supplements, *JAMA Int Med.* 173(5): 355-361.

¹⁰ Bolland *et al.*, 2011 Calcium supplements with or without vitamin D and risk of cardiovascular events: reanalysis of the Women's Health Initiative limited access dataset and meta-analysis. *Brit Med J*, 342:d2040

¹¹ Li *et al.*, 2012 Associations of dietary calcium intake and calcium supplementation with myocardial infarction and stroke risk and overall cardiovascular mortality in the Heidelberg cohort of European Prospective Investigation into Cancer and Nutrition study (EPIC-Heidelberg). *Heart* 98:920-5.

the risk for adverse cardiovascular events,^{12,13} these results have been questioned due to the fact the cardiovascular outcomes were not a primary endpoint of these trials.^{14,15,16} The lack of a clear mechanism underlying the purported increased cardiovascular risk has also not been demonstrated, further calling into question the biologic plausibility of calcium producing these events. Further, findings from a recent randomized controlled clinical trial conducted in a cohort of elderly women demonstrate that calcium supplementation did not increase either subclinical or clinical atherosclerosis.¹⁷ Results from other studies examining the effect of calcium supplementation (alone or with Vitamin D) are also consistent with this.^{18,19,20}

CHPA members marketing dietary supplements are committed to providing quality products manufactured according to current Good Manufacturing Practices (GMPs), labeled appropriately per regulation, and advertised in a responsible manner. CHPA also encourages all consumers choosing to purchase dietary supplements to consult with their healthcare provider prior to beginning use of these products. For those individuals not obtaining sufficient amounts of calcium through regular dietary intake, use of a calcium-containing dietary supplement represents an excellent way to maintain the current Recommended Dietary Allowance for this mineral.

¹² Paziana and Pazianas, Calcium supplements controversy in osteoporosis: a physiological mechanism supporting cardiovascular adverse effects. *Endocrine*. 2015;48(3):776-8.

¹³ Chrysant and Chrysant, Controversy regarding the association of high calcium intake and increased risk for cardiovascular disease. *J Clin Hypertens* 2014;16(8):545-50

¹⁴ Barice *et al.*, 2015 Calcium and Vitamin D Supplementation: Facts and Myths, *J Cardiovasc Pharm Ther*. 20(1): 9-10.

¹⁵ Wang *et al.*, 2012 Calcium intake and risk of cardiovascular disease: a review of prospective studies and randomized clinical trials. *Am J Cardiovasc Drugs*, 12(2):105-16.

¹⁶ Heaney *et al.*, A review of calcium supplements and cardiovascular disease risk *Adv Nutr*. 2012;3(6):763-71.

¹⁷ Lewis *et al.*, 2014 The Effects of 3 Years of Calcium Supplementation on Common Carotid Artery Intimal Medial Thickness and Carotid Atherosclerosis in Older Women: An Ancillary Study of the CAIFOS Randomized Controlled Trial *J Bone Min Res* 29(3): 534-41

¹⁸ Manson *et al.*, 2010 Calcium/Vitamin D Supplementation and Coronary Artery Calcification in the Women's Health Initiative, *Menopause* 17(4): 683-91.

¹⁹ Wang *et al.*, 2010 Relationships between vascular calcification, calcium metabolism, bone density, and fractures. *J Bone Miner Res*. 25(12):2777-85.

²⁰ Samelson *et al.*, 2012 Calcium intake is not associated with increased coronary artery calcification: the Framingham Study *Am J Clin Nutr* 96(6): 1274-80.

CHPA agrees with the conclusions from the recently conducted review by the NOF Expert Panel that currently there is insufficient evidence to suggest that calcium intake (either from food or dietary supplements) has any influence on the risk of hypertension, cardiovascular disease and mortality.

Respectfully submitted,

A handwritten signature in blue ink that reads "Jay Sirois". The signature is written in a cursive style with a large initial "J" and "S".

Jay Sirois, Ph.D.