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Council for Responsible Nutrition

The Science Behind the Supplements

FOR IMMEDIATE RELEASE

SCIENTIFIC EXPERTS CALL FOR INCREASED VITAMIN D UL

—Newly-Published Risk Assessment Supports Safety of Higher Intakes

Needed to Reap Additional Health Benefits—

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WASHINGTON, D.C., *January 22, 2007* — Four nutrition experts, including two Council for Responsible Nutrition (CRN) scientists and two of the world's pre-eminent vitamin D researchers, are urging the Food and Nutrition Board (FNB) to raise the vitamin D Tolerable Upper Intake Level (UL) five-fold, based on a safety evaluation of the latest scientific research that shows this vitamin to be safe at intake levels much higher than its current UL. John Hathcock, Ph.D., and Andrew Shao, Ph.D., both of CRN, and Reinhold Vieth, Ph.D., of Mount Sinai Hospital, Toronto, and Robert Heaney, M.D., of Creighton University, have co-authored a vitamin D risk assessment using the FNB method and published in the *American Journal of Clinical Nutrition* (AJCN) this month (Jan 2007; 85: 6-18). The paper concludes the safety profile of vitamin D should safely permit raising the UL for vitamin D to 250 μg (10,000 IU) per day from the current UL of 50 μg (2,000 IU) per day.

"The UL established by the FNB in 1997 for vitamin D is outdated. It is not based on current evidence and is viewed by many in the scientific community as being too restrictive—limiting research, commercial development, and optimization of nutritional policy," noted Dr. Vieth. "An ample collection of human clinical trial data published since the 1997 recommendation was made supports a significantly higher UL."

The call for FNB to re-evaluate the UL is particularly timely, given increased consumer interest in the nutrient following a number of recent studies showing benefit for vitamin D associated with levels beyond what is typically provided in a multivitamin and most fortified foods. Additionally, the Food and

Drug Administration (FDA) recently issued a proposed rule to allow the inclusion of vitamin D in the approved calcium and osteoporosis health claim.

Although many experts have been calling for a revision of the vitamin D UL in recent years, the AJCN risk assessment review article is the first to provide a quantitative basis and recommendation for an actual revised UL value. For the vitamin D risk assessment, Drs. Hathcock, Shao, Vieth and Heaney considered 21 relevant, well-designed human clinical trials using a vitamin D dose substantially above the current range of adequate intake (AI) levels of between 5 μ g (200 IU) and 15 μ g (600 IU) per day for different populations. Collectively, the absence of toxicity in these trials conducted in healthy adults that used a vitamin D dose \geq 250 μ g (10,000 IU vitamin D₃) per day supports the confident selection of this value as the UL.

Dr. Hathcock noted that the term UL does not suggest that nutrient intakes above the level identified are unsafe, nor does it constitute a recommended intake. The UL simply identifies a level of daily intake at which there is no known toxicity and at which there is sufficient evidence of safety for the nutrient.

"New data continue to emerge regarding the health benefits of vitamin D beyond its role in bone health," said Dr. Heaney. "The intakes associated with those benefits suggest a need for levels of supplementation, food fortification, or both that are higher than what is currently contained in most products. The safety profile of vitamin D demonstrated by our risk assessment should encourage the FNB to increase the UL for vitamin D in order to facilitate the realization of the benefits this vitamin can confer."

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Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement industry ingredient suppliers and manufacturers. CRN members voluntarily adhere to a strong code of ethics, comply with dosage limits and manufacture dietary supplements to high quality standards under good manufacturing practices.