

*Statement by:*

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*Before the*

Committee on Government Reform  
U.S. House of Representatives

*Regarding:*

Dietary Supplements: Nature's Answer to  
Cost Effective Preventative Medicine

*Date:*

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Mr. Chairman. My name is Al Dobson, Ph.D. I am a Senior Vice President for the Lewin Group. Thank you for the opportunity to present key findings of a study that The Lewin Group conducted for the Dietary Supplement Education Alliance. The purpose of this study is threefold: (1) to critically review the research evidence for five specific dietary supplements, (2) to develop estimates of changes in healthcare utilization and the associated health care expenditure savings that could result from daily use of two of these supplements, and (3) for the three supplements where there is emerging evidence, to suggest areas of future research that would fill existing knowledge gaps. In doing so we sought to determine if a given supplement had an effect on biological markers which lead to physiological effects and ultimately produced economic effects from reduced health care utilization. Supplements covered in this study include (1) **calcium (with Vitamin D)**, (2) **folic acid**, (3) **omega-3 fatty acids**, (4) **glucosamine**, and (5) **saw palmetto**.

The Lewin Group developed estimates of potential cost savings that could result from daily use of only those supplements for which the highest standard of evidence exists at this time, and for which the Food and Drug Administration (FDA) has approved health claims. As the literature on supplements evolves and matures the evidence often becomes more conclusive and more supportive of evidence based decision making. Cost estimates were developed for calcium (with Vitamin D) and folic acid, where in each case there is significant scientific agreement as to the improvement in health status. For these two supplements conservative estimates of healthcare expenditure savings were developed for specific relevant outcomes. For calcium with vitamin D, estimates of savings for avoided hip fractures among over age-65 were developed. For folic acid, estimates of savings

from avoided incidences of babies being born with neural tube defects (NTD) were developed.

### **Key Study Findings**

- **CALCIUM (with Vitamin D):** Daily intake of 1200 mgs of calcium with vitamin D could result in 734,000 fewer hip fractures among the population age-65 and over and could save an estimated \$13.9 billion over a five-year period. The Lewin Group used Congressional Budget Office (CBO-type) cost accounting methodology to estimate the five-year (2005-2009) **net savings** in hospital, nursing facility, and physician expenditures resulting from a reduction in the occurrence of hip fractures among the age-65 and over population. Over one third of adults age-65 and over experience falls each year. Among injuries from falls, hip fractures cause the most severe health problems and the greatest number of deaths. Hip fractures also tend to be the most costly among injuries because they require in-hospital surgical procedures to repair the hip and nearly 50 percent of these operations result in a prolonged stay in a nursing home. The body of research directed toward the health benefits of increased calcium intake spans more than 30 years. The evidence reflects sufficient consistency and validity such that the United States Public Health Service and the Food and Drug Administration endorse informed use of calcium supplements in established public health policies.
- **FOLIC ACID:** There are 64 million women of childbearing years in the United States. If an additional 10.5 million, or 25 percent of those not currently taking folic

acid, began taking 400 mcg. of folic acid on a daily basis prior to conception, the Lewin Group estimates that at least 600 babies would be born without Neural Tube Defects with an associated annual lifetime saving of as much as \$321.9 million. In 2004, the total lifetime cost of a baby with Neural Tube Defect is roughly \$532,000, a cost which includes direct medical care, therapies and equipment, and special education. In the United States there are about 4 million live births annually. Neural Tube Defects occur in one of every 1,000 pregnancies. The estimated five-year (2005-2009) savings, taking into account the very low cost of the supplement, is \$1.3 billion in lifetime costs of caring for babies born with neural tube defects. Longstanding and extensive research with supporting conclusions led the United States Public Health Service, Institute of Medicine, and Food and Drug Administration to establish recommendations and public health policies relating to folic acid intake and food fortification.

- **OMEGA-3 FATTY ACID:** The Lewin Group found consistent evidence that omega-3 fatty acids help reduce deaths from cardiovascular disease. Omega-3 fatty acids are also demonstrated as helping to lower blood pressure, may reduce the risk of re-blockage after an angioplasty, may increase exercise capacity in people with coronary atherosclerosis, and may reduce the risk associated with irregular heartbeats. However, at this time the specific effects on different cardiovascular disease outcomes (especially myocardial infarction and stroke) are uncertain. As recently as March 2004, the Agency for Healthcare Research and Quality (AHRQ) released a systematic review of the literature to assess the benefits of omega-3 fatty acids on cardiovascular disease outcomes. AHRQ found that studies of omega-3 fatty acids

were heterogeneous in that they examined different forms of omega-3 fatty acids, including dietary and supplemental fish oil, and varying combinations from plant sources. Also, studies tended to report on the different outcomes inconsistently. AHRQ concluded that focused and well- designed multicenter random clinical trials are now needed to validate earlier promising results and fill in any knowledge gaps. Recognizing the potential health benefits related to increased consumption of omega-3 acids, as recently as September 8, 2004 the Food and Drug Administration announced the availability of a qualified health claim for reduced risk of coronary heart disease on conventional foods that contain omega-3 fatty acids. Our recommendation is to pursue these investigations in order to further advance the knowledge base concerning the health benefits of omega-3 fatty acids.

- **GLUCOSAMINE:** Glucosamine has been shown to have anti-inflammatory effects and is believed to repair and maintain cartilage. To date, however, clinical studies on glucosamine have not conclusively demonstrated reductions in health service utilization that result from these clinical benefits. In order to further advance the science, the National Institutes of Health, National Center for Complimentary and Alternative Medicine (NCCAM) is now supporting two randomized double-blind studies of glucosamine. In 1999, approximately 10 million adults reported being diagnosed with osteoarthritis. Additionally, over 5 million adults reported having knee joint pain, swelling, and stiffness; about 25 percent of those with osteoarthritis reported having all three knee joint symptoms. Traditional treatments, most often anti-inflammatory drugs and pain relievers, produce variable results and may cause

significant toxicity. The use of complementary and alternative therapies in the treatment of osteoarthritis has become more widespread, and particular interest has focused on glucosamine.

- **SAW PALMETTO:** Preliminary findings from our review of randomized clinical trials of the effects of saw palmetto for alleviating the symptoms of benign prostatic hyperplasia (BPH) indicate that use of the herb yields slight to moderate improvement in symptoms for men with this chronic urinary syndrome. Benign prostatic hyperplasia is the most common morbid medical condition in men and is responsible for some urinary symptoms in most men over the age of 50 and is generally treated with alpha-adrenergic blocking agents, finasteride, surgical interventions, or no specific therapy. Currently the National Center for Complementary and Alternative Medicine (NCCAM) is conducting a randomized, double-blind, placebo controlled clinical trial of the safety and efficacy of saw palmetto, with careful attention to the methodological deficiencies of prior studies.

Surveys of dietary intake and physical and laboratory data reveal that the typical American diet does not always provide a sufficient level of nutrients to support optimal health. The *Nutrition and Your Health: Dietary Guidelines for Americans* acknowledges that some Americans may need a vitamin and/or mineral or other supplement to meet specific nutrient needs.

The overall conclusion of this study is that in certain instances, supplements are an inexpensive and safe way to improve health status and reduce health care expenditures. In these cases, the role of public policy to support their use is unambiguous. In other

instances, although the available evidence is less definitive, it warrants attention from health care providers and their patients, as well as continued investment of public financing for additional research.

With this study, the Lewin Group hopes that we have assisted the Dietary Supplement Education Alliance, the members of Congress, and you, Mr. Chairman, to better understand the benefit of these dietary supplements to our national population's health and our national economic health as well.

Mr. Chairman. Thank you for the opportunity to present these findings from The Lewin Group's study. A copy of the summary report, on which this testimony is based, is provided for your consideration.