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DIETARY SUPPLEMENTS: NATURE'S ANSWER TO COST EFFECTIVE PREVENTATIVE MEDICINE

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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DIETARY SUPPLEMENTS: NATURE'S ANSWER TO COST EFFECTIVE PREVENTATIVE MEDICINE

WEDNESDAY, SEPTEMBER 22, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the subcommittee) presiding.

Present: Representatives Burton and Watson.

Staff present: Mark Walker, chief of staff; Mindi Walker, Brian Fauls, and Dan Getz, professional staff members; Nick Mutton, press secretary; Danielle Perraut, clerk; Sarah Despres, minority counsel; Richard Butcher, minority professional staff member; and Cecelia Morton, minority office manager.

Mr. BURTON. Good morning. A quorum being present, the Subcommittee on Human Rights and Wellness will come to order. I ask unanimous consent that all Members and witnesses' written and opening statements be included in the record. And without objection, so ordered.

I ask unanimous consent that all articles, exhibits, and extraneous or tabular materials referred to be included in the record. Without objection, so ordered.

In the event of other Members attending the hearing, I ask unanimous consent that they be permitted to serve as a member of the subcommittee for today's hearing. And without objection, so ordered.

We have other Members that will be coming very shortly, Ms. Watson in particular. And for those who aren't here, they will get transcripts of the hearing.

I, along with millions of Americans, firmly believe that dietary supplements have been shown through credible scientific research and historical use to be of immeasurable benefit to human health.

As a regular consumer, I know firsthand the health benefits of using dietary supplements on a daily basis. Consequently I proudly serve as cochairman of the Congressional Complementary and Alternative Medicine Caucus, the CAM Caucus, along with my colleague, Representative Dennis Kucinich of Ohio, in the House, and Senators Orrin Hatch of Utah in the Senate, and Tom Harkin of Iowa in the Senate. They have been true champions on these issues for some time.

Together we have worked hard, in a bipartisan fashion, for the continued research and safety of all dietary supplements manufactured and sold in the United States. It remains our top priority to ensure that only the highest quality of products are made available to the American consumers.

Given my role as cochairman of the CAM Caucus, as well as my duties as chairman of the Subcommittee on Human Rights and Wellness, I am particularly concerned about how these products can be used as preventatives, and preventative measures, to combat the multitude of life-threatening and debilitating medical conditions like cardiovascular disease, cancer, osteoporosis, and even preventable birth defects in infants.

The subcommittee has invited some of the foremost experts on nutrition to discuss the proven health benefits of regular supplement usage. Dr. Jeffrey Blumberg, professor at the Friedman School of Nutrition Science and Policy at Tufts University is with us today to explain the role of folic acid and other dietary supplements in the promotion of health and prevention of chronic diseases.

The subcommittee also has the pleasure of hearing testimony from Dr. Barbara Levine, an associate professor of nutrition and medicine at the Weill College of Medicine at Cornell University, who will discuss two of the nutrients she has studied for a majority of her career, Omega–3 fatty acids and calcium. Dr. Levine will also explain how those two nutrients are needed throughout the entire life cycle in the development and growth of the human body, in addition to their use for prevention and treatment of a variety of diseases.

In addition to the scientifically proven health benefits of using dietary supplements correctly to promote a healthier lifestyle and curb disease, these products can also offer substantial cost savings for our long-term national health care expenditures. And that is one of the things that isn't talked about enough.

During our hearing today a new study will be released regarding the cost savings of dietary supplements on the U.S. health care system. Dr. Allen Dobson, senior vice president of the Levin Group, an independent health care consulting firm, is here with us today to discuss the conclusions of his study, which demonstrates that certain supplements provide an inexpensive and safe way to improve overall personal health and reduce health care expenditures.

A recent report published by the Institute of Medicine [IOM], estimates that American consumers spend over $18 billion annually on the over 29,000 supplements sold in the United States. In 1994, Congress passed, and the President signed into law, the Dietary Supplement Health Education Act [DSHEA]. DSHEA prescribes the framework for how the Federal Government ensures the safety and the efficacy of dietary supplements sold in the United States.

Prior to DSHEA, dietary supplements were treated and regulated as traditional food products. Seeing a need for the Federal Government to address the American consumer's growing interest in dietary products, in conjunction with public safety, Congress overwhelming passed this legislation to make certain that all dietary health products sold in the United States are held to the highest and most stringent quality standards.

DSHEA ensures the safety of dietary supplements by requiring manufactures to follow standards called good manufacturing practices [GMPs]. Essentially all ingredients in supplements sold in the United States must be previously approved by the Food and Drug Administration and listed on the products bottle label. In addition, distributors must follow strict guidelines on all claims that are made in regard to a particular product. This ensures consumers are equipped with the most accurate information regarding their supplements.

Dr. Paul Coates, the Director of the Office of Dietary Supplements at the National Institutes of Health [NIH], is here to talk about the Federal Government's research into dietary supplements and how these products have been shown to provide for a healthier lifestyle both in children and in adults.

In addition, Mr. Elliott Balbert, the president of the Dietary Supplement Education Alliance, will be testifying before the subcommittee to discuss the supplement industry's efforts and continued support for the overwhelming need to ensure that consumers have access to balanced, science-based facts about dietary supplements.

And, finally, we have the distinct pleasure of having a distinguished star of the stage and screen, whom I think is beautiful and have admired her for a long, long time, testifying before our subcommittee today. I saw her in Taxi a long time ago, and she looks so young, it just doesn't seem possible. Marilu Henner is here to talk about her personal experiences using dietary supplements in attaining and maintaining optimal health. Ms. Henner has not only personally benefited from supplement usage, but has also served as a health advocate, and is the author of six books on how to live a healthier lifestyle.

Whether taking a multivitamin, herbal product or a specialty supplement, people can and do live healthier lives and save money in long-term health care costs by supplementing their diets.

I would like to thank all of our witnesses for their participation in this hearing, and I look forward to hearing their testimony.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement of Chairman Dan Burton
Government Reform Committee
Subcommittee on Human Rights & Wellness
Dietary Supplements: Nature's Answer to Cost-Effective Preventative Medicine
Wednesday, September 22, 2004

I, along with millions of Americans, firmly believe that dietary supplements have been shown through credible scientific research and historical use to be of immeasurable benefit to human health.

As a regular consumer, I know firsthand the health benefits of using dietary supplements on a daily basis. Consequently, I proudly serve as Co-Chairman of the Congressional Complementary and Alternative Medicine (CAM) Caucus, along with my colleague Representative Dennis Kucinich of Ohio here in the House, and Senators Orrin Hatch of Utah and Tom Harkin of Iowa, who have been true champions on these issues in the Senate.

Together, we have worked hard in a bi-partisan fashion for the continued research and safety of all dietary supplements manufactured and sold in the United States. It remains our top priority to ensure that only the highest quality of products are made available to American consumers.

Given my role as Co-Chair of the CAM Caucus, as well as my duties as Chairman of the Subcommittee on Human Rights and Wellness, I am particularly concerned with how these products can be used as preventative measures to combat a multitude of life-threatening and debilitating medical conditions like cardiovascular disease, cancer, osteoporosis, and even preventable birth defects in infants.

The Subcommittee has invited some of the foremost experts on nutrition to discuss the proven health benefits of regular supplement usage. Dr. Jeffrey Blumberg, Professor at the Friedman School of Nutrition Science and Policy at Tufts University is with us today to explain the role of folic acid and other dietary supplements in the promotion of health and prevention of chronic diseases.

The Subcommittee also has the pleasure of hearing testimony from Dr. Barbara Levine (La-Veen), an Associate Professor of Nutrition in Medicine at the Weill (Wheel) College of Medicine at Cornell University, who will discuss two of the nutrients she has studied for a majority of her career: Omega – 3 Fatty Acids and Calcium.

Dr. Levine (La-veen) will also explain how these two nutrients are needed throughout the entire life cycle in the development and growth of the human body in addition to their use for prevention and treatment of a variety of diseases.

In addition to the scientifically proven health benefits of using dietary supplements correctly to promote a healthier lifestyle and curb disease, these products

can also offer substantial cost savings for our long-term National health care expenditures.

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A recent report published by the Institute of Medicine (IOM) estimates that American consumers spend over $18 billion annually on the over 29,000 supplements sold in the United States. In 1994, Congress passed, and the President signed into law the *Dietary Supplement Health Education Act*, commonly referred to as DSHEA. DSHEA prescribes the framework for how the Federal government ensures the safety and efficacy of dietary supplements sold in the United States.

Prior to DSHEA, dietary supplements were treated and regulated as traditional food products. Seeing a need for the Federal government to address the American consumer's growing interest in dietary products in conjunction with public safety, Congress overwhelmingly passed this legislation to make certain that all dietary health products sold in the United States are held to the highest and most stringent quality standards.

DSHEA ensures the safety of dietary supplements by requiring manufacturers to follow standards called "Good Manufacturing Practices," or GMPs. Essentially, all ingredients in supplements sold in the United States must be previously approved by the FDA and listed on the product's bottle label. In addition, distributors must follow strict guidelines on all claims that are made in regard to a particular product – this ensures consumers are equipped with the most accurate information regarding their supplements.

Dr. Paul Coates, Director of the Office of Dietary Supplements at the National Institutes of Health (NIH), is here to talk about the Federal government's research into dietary supplements, and how these products have been shown to provide for a healthier lifestyle both in children and adults.

In addition, Mr. Elliot Balbert, the President of the Dietary Supplement Education Alliance will be testifying before the Subcommittee to discuss the supplement industry's efforts and continued support for the overwhelming need to ensure that consumers have access to balanced, science-based facts about dietary supplements.

Finally, we have the distinct pleasure of having a distinguished star of the stage and screen testifying before our Subcommittee today. Marilu Henner, is here with us to talk about her personal experiences using dietary supplements in attaining and maintaining optimal health. Ms. Henner has not only personally benefited from

supplement usage, but has also served as a health advocate and is the author of 6 books on how to live a healthier lifestyle.

Whether taking a multi-vitamin, herbal product, or specialty supplement, people can and do live healthier lives and save money in long-term health costs by supplementing their diets. I would like to thank all of our witnesses for their participation in this hearing, and I look forward to hearing their testimony.

Mr. BURTON. With that, we will start with Dr. Coates.

Dr. Coates, if you would come forward and stand so I can swear you in, please.

[Witness sworn.]

Mr. BURTON. Do you have an opening statement, Doctor?

Mr. COATES. I do.

Mr. BURTON. If we could, I would like to try to admonish the witnesses to try to keep their statements to 5 minutes so we would have more time for questions if possible.

STATEMENT OF PAUL COATES, Ph.D., DIRECTOR, OFFICE OF DIETARY SUPPLEMENTS, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. COATES. Thank you very much. Mr. Chairman, I am Paul Coates. I direct the Office of Dietary Supplements at the National Institutes of Health. I appreciate the opportunity to appear before you today to talk about NIH efforts and research on dietary supplements.

I appeared before this committee 2 years ago to give you details about some key NIH initiatives and to highlight the opportunities as well as the challenges associated with developing strong science in the field of dietary supplements. These are products that are used widely by American consumers for their potential health benefits, often in combination with other lifestyle measures such as diet and physical activity. Their potential to improve health and to prevent disease has been realized when some have been put to modern scientific testing. Clear examples of this are folic acid, in the prevention of neural tube defects, and calcium to reduce the risk of osteoporosis.

It is important to keep in mind, though, that others have not undergone rigorous scientific testing to establish their efficacy and safety. Some are currently under active investigation at the NIH, as I will mention in a moment.

In the preamble, or in the invitation, you identified five supplements as being of particular interest today: folate, calcium, omega–3 fatty acids, glucosamine, and saw palmetto. I would like to give you a snapshot of some ongoing NIH-funded research efforts related to these ingredients.

With respect to folate, NIH has funded and continues to fund considerable research examining its role in the prevention of chronic diseases such as cancer and heart disease. In addition to these many projects, which I would be pleased to share with you in more detail, I draw your attention to another current trial that looks at the impact of folate and other B vitamins on slowing the rate of cognitive decline in Alzheimer's disease.

With respect to calcium, the NIH has a considerable investment in clinical research. In addition to the many studies supported by NIH over the years on calcium and bone health, one current trial that I would like to draw to your attention is a trial called supplemental calcium in overweight people, currently under way at the NIH to examine the effects of calcium supplementation on weight reduction.

With respect to omega–3 fatty acids, the Office of Dietary Supplements has sponsored a series of evidence reports in collaboration with the Agency for Health Care Research and Quality, on the health effects of omega–3s for a number of conditions. One report in particular, the one on cardiovascular disease, concluded that there was substantial evidence for benefit of omega–3 fatty acids in the secondary prevention of heart disease, but that there was considerably less evidence for an effect on primary prevention; that is, in the general population.

We view that as an opportunity, not a barrier, and as a result of this report, the National Heart-Lung and Blood Institute, along with the Office of Dietary Supplements, convened a working group earlier this year to assess future research needs related to coronary disease prevention with omega–3s. The working group recently made its recommendations, which are currently being pursued at the NIH.

With respect to glucosamine, a clinical trial is currently under way looking at the effect of glucosamine and chondroitin sulfate for knee osteoarthritis. It has now met its recruitment goals of nearly 1,600 participants and scheduled to be completed within a year.

Finally, a clinical trial of saw palmetto and African plum for urinary symptoms in men was recently funded and should provide some very informative results.

I would like to comment at this point that the evidence for benefit is stronger for some of these supplements than it is for others. I would also like to point out that research efforts need to continue apace in all of these areas, and that NIH remains committed to encouraging and supporting the best science in this area.

Between 1999 and 2003, the years for which we have these data, NIH invested roughly $770 million to support research related to dietary supplements. About a quarter of that was devoted to studies of the five supplement ingredients that I have cited above.

Let me briefly tell you a little about the Office of Dietary Supplements. We were authorized by the Dietary Supplement Health and Education Act of 1994, and came into existence at the NIH in 1995. Our mission is to identify and foster research on the health benefits and the risks of supplements.

We have a strategic plan in place, and I am pleased to announce that the strategic plan for the next 5 years has now been published, and it can be found on the Office of Dietary Supplements' Web site.

As a result of increases in funding for the Office by Congress, from $3.5 million in 1999 to about $26 million year, we have expanded our role in a number of important activities. This year we cofund 90 research grants with other institutes at the NIH, and among those a number of dietary supplement research centers that we fund across the country that specialize in botanical dietary supplements.

Let me give you four brief examples of other efforts that we do in collaboration with other agencies, both within and outside the NIH. The National Health and Nutrition Examination Survey looks at supplement use in a health context, and is conducted by the CDC. We significantly support that, along with collaborators at the FDA, the National Institute of Standards and Technology, and a

number of private sector organizations, including the dietary supplement industry. We administer a program to develop, validate and disseminate analytical methods and reference materials for dietary supplements.

And, finally, I wanted to mention that as part of our evidence-based review program, which we conduct in collaboration with the Agency for Healthcare Research and Quality, we have two others that are currently under way, two evidence reports, in addition to the omega–3 ones I cited. One is on vitamin D adequacy in health, and the other is on the role of antioxidants and B vitamins in the age-related neurodegenerative disorders. These are all collaborative efforts. It is a key way in which to get research done in this area, in my opinion.

Mr. Chairman, I thank you for the opportunity to review the status of dietary supplement research at the NIH, and I would be happy to answer your questions.

[The prepared statement of Mr. Coates follows:]

Testimony
Before the Subcommittee on Human Rights and Wellness
Committee on Government Reform
United States House of Representatives

Ongoing Research on Dietary Supplements at the National Institutes of Health

Statement of
Paul M. Coates, Ph. D.
Director
Office of Dietary Supplements
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
on Wednesday, September 22, 2004

Mr. Chairman and Members,

Thank you for the opportunity to appear before you today representing the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH). I became Director of ODS in late 1999, and I had the pleasure of appearing before the Committee two years ago, in July 2002. At that time, I provided you with some details about the activities of ODS and highlighted both the opportunities and the challenges associated with developing good science in the field of dietary supplements.

Prior to highlighting ODS and other NIH efforts related to five supplement ingredients that you identified – folate, calcium, omega-3 fatty acids, glucosamine, and saw palmetto – I want to give you a brief update of our continuing and emerging collaborative investigations of dietary supplements, particularly as they relate to reducing the risk of chronic diseases.

Health Effects of Dietary Supplement Ingredients

Dietary supplements are widely used by American consumers, often in combination with other lifestyle measures such as diet and physical activity, for their potential benefits in health promotion and disease prevention. Surveys, such as the National Health and Nutrition Examination Survey (NHANES), which is conducted by the Centers for Disease Control and Prevention (CDC) and funded in part by NIH organizations including ODS, show that 50% or more of American adults use supplements on a regular basis, primarily vitamins and minerals, but herbal and other supplements as well[1]. There are many hopes pinned on dietary supplements for the improvement of health and prevention of disease, hopes that have been realized when some of them have been put to modern scientific testing. Examples of these include:

- Folic acid to reduce the risk of neural tube defects, one of the most common birth defects. As a result of this research, the CDC and other partners in the National Folic Acid Campaign aim to educate all women of childbearing age to consume 400 micrograms of synthetic folic acid daily from vitamin supplements and/or fortified foods in addition to eating food folate in a healthful diet;
- Calcium to reduce the risk of osteoporosis. The NIH Consensus Development Conference in 1997 concluded that while the preferred source of calcium is through calcium-rich foods, both calcium supplements and calcium-fortified foods are other means by which optimal calcium intake can be reached for those who cannot meet this need by eating conventional foods;
- Iron supplementation during pregnancy to prevent maternal anemia and delivery of premature infants;
- Vitamin B-12 supplementation for those (particularly among the elderly) who cannot readily absorb food-bound vitamin B-12;
- Vitamin and antioxidant supplementation to prevent progression of macular degeneration; and

[1] Radimer K, Bindewald B, Hughes J, Irvin B, Swanson C, Picciano MF: Dietary supplement use by US adults: Data from the National health and Nutrition Examination Survey, 1999-2000. Amer J Epidemiol 160:339-349, 2004.

- Supplements promoting antioxidant activity generally to reduce the risk of oxidative damage from exposure to environmental agents.

Of the approximately 30,000 dietary supplements on the market in the United States, there are many that have not undergone the rigorous scientific testing needed to establish their efficacy and safety. Some are under active investigation at the NIH, including:

- Ginkgo biloba: does it prevent decline of cognitive function in older individuals?
- Dietary phytoestrogens: do they prevent bone loss in postmenopausal women?
- Selenium and vitamin E: alone or in combination, do they prevent prostate cancer?; and
- Glucosamine and chondroitin: alone or in combination, do they diminish the pain associated with knee osteoarthritis?

Other dietary supplements have been shown to be potentially harmful to some individuals; for example, research has shown that beta-carotene, instead of reducing cancer risk, may actually increase lung cancer incidence among cigarette smokers. For still others, there are signals of concern (e.g., from adverse event reports) that need to be followed up in a scientifically sound manner.

The Expanding Role of ODS in Dietary Supplement Research

ODS was mandated by the Dietary Supplement Health and Education Act of 1994 (DSHEA) and was formally installed in the Office of the Director of NIH in 1995. Its mission, based on a comprehensive strategic planning process, is to "identify and foster research on the health benefits and risks of these substances based on the merit of the underlying scientific evidence."

Last year, ODS re-evaluated its Strategic Plan with input from a wide range of stakeholders. I am pleased to announce that this Plan has just been published and that it can be found on the ODS website (http://ods.od.nih.gov). The Strategic Planning process helped us considerably in assessing how far we had come in the past five years and in guiding ODS activities for the future. ODS has been able to embark on a number of important activities, including:

- Co-funding of dietary supplement research grants with other Institutes and Centers (ICs) at NIH. In FY 2004, ODS has been able to co-fund 90 grants with 15 NIH ICs for a total investment of approximately $15 million;
- Sponsoring conferences and workshops, again most often in collaboration with other ICs; since the inception of this program, ODS has sponsored nearly 100 such events;
- Developing a series of fact sheets on vitamins and minerals, in collaboration with the NIH Clinical Center;
- Initiating two important database efforts: the *International Bibliographic Information on Dietary Supplements (IBIDS)*, developed jointly with the National Agricultural Library of the U.S. Department of Agriculture (USDA), which cites roughly 750,000 references to the world's literature, and *Computer Access to Research on Dietary Supplements (CARDS)* to track the Federal investment in

dietary supplement research. The current CARDS data set describes the NIH investment from FY 1999 to FY 2003; over that period of time, NIH alone has invested over $770 million in supporting nearly 2600 research projects related to dietary supplements; and

- An especially important activity of ODS is its program of comprehensive Dietary Supplement Research Centers around the country. There are six of these multidisciplinary Centers (located at Purdue University/University of Alabama at Birmingham, Iowa State University/University of Iowa, University of Illinois at Chicago, University of California at Los Angeles, University of Arizona, and University of Missouri/Missouri Botanical Garden) whose primary focus is botanical dietary supplements. The Centers are jointly funded with the National Center for Complementary and Alternative Medicine (NCCAM) and the National Institute of Environmental Health Sciences (NIEHS); other NIH components, including the National Institute of General Medical Sciences (NIGMS) and the Office of Research on Women's Health (ORWH), also participate in funding these Centers.

More recently, the budget for ODS has grown, from $3.5 million in FY 1999 to $26 million in FY 2004. This has permitted expansion of our research, education, and communications agenda into new and important areas:

- Evidence-based reviews of dietary supplement efficacy and safety, in collaboration with other NIH ICs and the Agency for Healthcare Research and Quality (AHRQ). (I will return to this activity later in my testimony.);
- Surveys of dietary supplement use, e.g., the NHANES conducted by the CDC;
- Development of a database of dietary supplement ingredients in collaboration with the USDA;
- Development, validation, and dissemination of analytical methods and reference materials for dietary supplements, in collaboration with the Food and Drug Administration (FDA) and a number of private sector organizations[2];
- Development of a formal program related to the role of dietary supplements in health promotion and reduction of risk for chronic diseases;
- Expansion of our information and communications program;
- Expansion of training and career development activities; and
- Participation in international research efforts.

In partnership with other NIH ICs, ODS funds research grants in areas such as:

- Folate-genome interactions in colorectal cancer;
- Zinc nutrition and brain development in Southern Ethiopia;
- Mechanisms of prostate cancer prevention by lycopene;
- Aging, vitamin E, and immune function;
- Chromium picolinate in the metabolic syndrome;
- Mitochondrial rRNA methylation and effects of ethanol and S-Adenosyl-L-Methionine (SAMe);

[2] Saldanha LG, Betz JM, Coates PM: Development of the analytical methods and reference materials program for dietary supplements at the National Institutes of Health. J AOAC Int. 87:162-165, 2004.

- Neuromodulatory effects of ginkgolides and bilobalides;
- Conjugated linoleic acid effects on lipid synthesis;
- Whether high dose B vitamins delay age-related decay; and
- The role of St. John's Wort in the management of minor depression.

ODS sponsors workshops and conferences, again in collaboration with other organizations both within and outside NIH. These meetings are valuable sources of information in assisting us to shape upcoming research activities. Some recent and upcoming conferences include:

- The Role of SAMe in Treatment of Alcoholic Liver Disease. This led to issuing a Request for Applications (RFA) in 2002 with the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and NCCAM; these 3 organizations jointly funded eight grants from this RFA;
- Diet, DNA Methylation Processes and Health, sponsored by the National Cancer Institute (NCI) with participation by ODS, NIEHS, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Child Health and Human Development (NICHD), and the FDA. This led to release of an RFA jointly sponsored by NCI and ODS and eventual funding of 10 grants;
- Three conferences on Dietary Supplement Use in Children, in Women, and in the Elderly (with NICHD, NCCAM, NIA, ORWH and others);
- Vitamin D and Health in the 21st Century, jointly sponsored by ODS and NICHD; and
- An NIH State-of-the-Science Conference on the Role of Multivitamins/ multiminerals in Chronic Disease Prevention, to be organized by the NIH Office of Medical Applications of Research with sponsorship from ODS and many other NIH ICs.

The development of other new areas of investigation relies on forging strategic partnerships with other agencies as well. A few current examples include Interagency Agreements with:

- The National Center for Health Statistics at CDC, to support improvements in the ability of NHANES to more accurately assess dietary supplement intake in the U.S., as well as biomarkers of supplement usage related to health outcomes;
- AHRQ, to develop evidence reports of dietary supplement efficacy and safety. The first of these, on ephedra efficacy and safety in weight management and athletic performance enhancement, was published in early 2003[3]; others have been completed (a series on the health effects of omega-3 fatty acids) or are underway on topics that include "Vitamin D Adequacy and Health" and

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[3] Shekelle PG, Hardy ML, Morton SC et al: Efficacy and safety of ephedra and ephedrine for weight loss and athletic performance: a meta-analysis. JAMA 289:1537-1545, 2003.

"Relationship between Antioxidants in Berries and B Vitamins and Age-related Neurodegenerative Disorders";

- FDA, to support the development and validation of analytical methods by the Association of Official Analytical Chemists (AOAC) International; and
- The National Institute of Standards and Technology (NIST) in the Department of Commerce, to support development of standard reference materials.

We have worked with partners in the private sector in a number of areas:

- Publication of an annual bibliography of outstanding research in dietary supplements, initially with the Consumer Healthcare Products Association. This effort, now fully under the auspices of ODS, is in its fifth year;
- Publication of "Botanical Pharmacognosy and the Microscopic Characterization of Botanical Raw Materials" by the American Herbal Products Association was supported in part by ODS;
- Publication of a summary of the conference "Dietary Supplement Use in the Elderly" in collaboration with the Foundation for the National Institutes of Health and Virgo Publishing Inc.;
- Publication of "What Supplements Are You Taking? Does Your Healthcare Team Know? It Matters and Here is Why", a brochure for the elderly, jointly produced by FDA and ODS in collaboration with a number of private sector organizations;
- Regular participation of ODS staff in educational and scientific sessions at industry meetings and expositions; and
- A crucial effort is engaging with industry – as well as other federal agencies, non-governmental organizations and academia – to develop, validate, and disseminate analytical methods and reference materials for dietary supplements.

I would like to stress a theme that runs through all of the activities that I have mentioned: all were developed in collaboration with other organizations, both within and outside the NIH. They could not have been accomplished otherwise. In my view, these collaborations are crucial to the advancement of science and dissemination of information in the area of dietary supplements. Further details of these and other interactions can be found on the ODS website (http://ods.od.nih.gov).

Let me now turn to the five supplement ingredients that you have identified as being of particular interest: folate, calcium, omega-3 fatty acids, glucosamine, and saw palmetto. I indicated earlier that the Federal investment in dietary supplement research has been extensive over the last five years. While the data are still being analyzed, I can tell you that, taken together, research on these five ingredients has accounted for roughly one-quarter of that investment. While much of the funding has been directed to basic research, increasing attention has been paid to conducting appropriate human studies. Some examples include:

Glucosamine

A clinical trial of glucosamine and chondroitin sulfate for knee osteoarthritis (Glucosamine/Chondroitin Arthritis Intervention Trial or GAIT), jointly sponsored by

NCCAM and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), has met its recruitment goals and is due to be completed within a year.

Saw palmetto
A clinical trial of saw palmetto and Pygeum africanum for urinary symptoms in men (Complementary and Alternative Medicine for Urinary Symptoms, or CAMUS) was recently funded by NIDDK, NCCAM, and ODS.

Omega-3 fatty acids
As part of its program of evidence-based reviews of dietary supplement efficacy and safety, ODS sponsored a series of AHRQ-contracted evidence reports of the health effects of omega-3 fatty acids for a number of conditions. Several of these have been published this year – on cardiovascular disease (CVD), asthma, and type 2 diabetes, among others – and several more will appear early in 2005. The evidence report on CVD concluded that there was substantial and strong evidence for a benefit of omega-3 fatty acids in the secondary prevention of CVD, but that there was considerably less evidence for an effect on primary prevention. Thus, while strong clues were obtained about the positive health effects of omega-3 fatty acids on the future risk of disease in people with existing CVD, the same cannot yet be said for the general population. As a result of this report[4], NHLBI and ODS convened a working group earlier this year to assess future research needs related to primary and secondary prevention in this area; the working group made recommendations for clinical trials necessary to answer important outstanding questions about omega-3 fatty acids[5]. These recommendations are currently being pursued.

Calcium
NIH funds considerable clinical research related to calcium. One intramural NICHD study that I would like to draw to your attention is the trial of Supplemental Calcium in Overweight People, which examines the health effects of calcium supplements in overweight adults. In addition, ODS has recently published a Fact Sheet on Calcium to inform consumers about the health benefits of adequate calcium intake[6]. All Fact Sheets that ODS issues are regularly reviewed and updated as necessary to reflect important advances in science.

Folate
Finally, based on results of the recently available NHANES data on folate and vitamin B-12, along with developments in methodology for their assessment, ODS is working with colleagues at NIH and other Federal agencies in evaluating the measures that are employed to determine health outcomes from intake of folate and vitamin B-12. There is particular interest in the elderly, in whom intake of these vitamins has been implicated in cognitive functioning and cardiovascular health.

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[4] http://www.ahrq.gov/clinic/tp/o3cardtp.htm
[5] http://www.nhlbi.nih.gov/meetings/workshops/omega3-summary.htm
[6] http://ods.od.nih.gov/factsheets/calcium.asp

Closing Remarks

Mr. Chairman and Members of the Committee, I thank you again for inviting me to review the accomplishments of the Office of Dietary Supplements at NIH, and to highlight some of its ongoing research opportunities and challenges. I would be happy to answer your questions.

Mr. BURTON. Do you take supplements?

Mr. COATES. That is a personal decision, and I do. But that doesn't extend beyond by personal decision.

Mr. BURTON. What does that mean?

Mr. COATES. I am not in a position to make recommendations to others.

Mr. BURTON. I see. But you do take supplements.

Mr. COATES. I take a multivitamin.

Mr. BURTON. Can you tell us a little bit about the risks associated by using dietary supplements, from your point of view?

Mr. COATES. I can tell you some of the issues that are raised. One in particular is the possible interaction of certain dietary supplement ingredients and other bioactive ingredients that people take, either other supplements or drugs. Occasionally there have been identified risks associated with that. People need to know about the possible interaction among these biologically active constituents.

Mr. BURTON. But the labeling on the bottles pretty much tells people who are taking those to be careful or consult a physician in the event that they think that there might be some counteractive——

Mr. COATES. Yes. That is certainly a goal for all of the potentially harmful interactions. I venture to say that we don't know everything that we need to know either about the benefits or the risks of dietary supplements, and our job is to try to identify those so that the best information can be made available to consumers.

Mr. BURTON. I see. But you don't see the need for the health agencies to take over complete control over supplements and all of that?

Mr. COATES. I am not sure I understand that question.

Mr. BURTON. Well, there have been some people who thought that DSHEA was something that we should not have passed in the Congress, and some of our health agencies say that all supplements should be regulated. You don't agree with that?

Mr. COATES. They are regulated.

Mr. BURTON. No. What I mean is they are not reviewed on a regular basis by the health agencies; i.e., Health and Human Services and FDA.

Mr. COATES. I think it is the FDA's responsibility to regulate dietary supplements using the existing law.

Mr. BURTON. Using the existing law. But you don't think there needs to be any changes in that?

Mr. COATES. The last time I testified here, Mr. Chairman, I think you asked me the same question, and I said that at the time that DSHEA was passed, that it was an effective and appropriate way to look at dietary supplements.

Sometimes things change. I think we have learned a lot about dietary supplements, and I am not advocating that there be any change. But I do think that it is appropriate for people to examine periodically what they are doing.

Mr. BURTON. But you are not advocating any change right now?

Mr. COATES. That is not my position.

Mr. BURTON. Good.

In your opinion, how has the passage of the dietary supplement—or DSHEA affected the FDA's enforcement powers over dietary supplements?

Mr. COATES. This is a tricky question for me to answer, since I am not in the FDA, and I am in a sister agency, and I don't know that I have any information that I can bring to bear on your question.

Mr. BURTON. OK. Could you please inform the subcommittee where you believe the issue of dietary supplements will be in 5 years if the funding for these research initiatives remain consistent or constant?

Mr. COATES. Thank you for—there is a question that I am in a much better position to be able to answer, since it relates to the research efforts, which really is what I do.

I think we are in a position where we can provide an enormous amount of information to American consumers about dietary supplements. There is a lot that still needs to be done.

What we understand about dietary supplements is quite variable. For some, we have very clear evidence of benefits. We also understand those circumstances in which individuals may be at risk, given exposure to certain supplements under some conditions. It is such a large body of knowledge that needs to be addressed. I think you alluded to the idea that there are 29,000 or so products in the marketplace. They are not, of course, all different from one another in terms of the ingredients.

But there is a lot that remains to be done, and I think it is incumbent upon us as a research agency to invest as much as we can in developing the right data set to inform consumers.

Mr. BURTON. Ms. Watson, I am sure, has questions. Would you be willing to have her submit those to you for the record, because she is not here. She had to go to a Democrat get-together, I guess, and she is in the front row, and she can't leave right now. But she will be here shortly, so we will have her submit those to you.

Mr. COATES. Thank you. I will be here for the rest of the hearing.

Mr. BURTON. Oh, good. Thank you. I am glad you decided to stay. I wish we had more government agencies that were willing to do that.

Mr. BURTON. OK. Our next panel is Allen Dobson, Ph.D., senior vice president of the Lewin Group. Would you come forward, Mr. Dobson.

Jeffrey Blumberg, Ph.D., professor at Friedman School of Nutrition Science and Policy at Tufts University; Barbara Levine, R.D., Ph.D., associate professor, nutrition in medicine, Weill College of Medicine, Cornell University; Elliott Balbert, president of the Dietary Supplement Education Alliance; and the ever popular Marilu Henner, TV and movie star, actress, author, and health advocate, and author of six books. I will have to read one of your books.

Would you all please rise so we can have you sworn.

[Witnesses sworn.]

Mr. BURTON. Dr. Dobson.

STATEMENTS OF ALLEN DOBSON, Ph.D., SENIOR VICE PRESIDENT, THE LEWIN GROUP; JEFFREY BLUMBERG, Ph.D., PROFESSOR, FRIEDMAN SCHOOL OF NUTRITION SCIENCE AND POLICY, TUFTS UNIVERSITY; BARBARA LEVINE, R.D, Ph.D., ASSOCIATE PROFESSOR OF NUTRITION IN MEDICINE, WEILL COLLEGE OF MEDICINE; ELLIOTT BALBERT, PRESIDENT, DIETARY SUPPLEMENTS EDUCATION ALLIANCE; AND MARILU HENNER, ACTRESS, NUTRITION AND DIET EXPERT

Mr. DOBSON. Mr Chairman, my name is Allen Dobson. I'm 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 has conducted for the Dietary Supplement Education Alliance.

The purpose of the study was threefold: to critically review the research evidence for five specific dietary supplements, to estimate changes in health care utilization and the associated health care expenditure savings that could result from the daily use of two of these supplements, and then for the other three supplements to recommend research that might be done in the future.

The five supplements that were covered in this study, calcium with vitamin D, folic acid, omega–3 fatty acids, glucosamine and saw palmetto, the Lewin Group developed estimates of potential cost savings that could result from the daily use of only two of these supplements for which the higher standard of evidence exists at this time. In effect, what we are doing is we were moving beyond the research and the literature, which speak to the efficacy of the supplements, and speaking to their cost-effectiveness in society. That is to say, if they are used appropriately, what savings might accrue to both the individuals and society? So in that sense the study results that we are presenting today are new.

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 for health care expenditure savings were developed for specific relevant outcomes.

Dr. Devonso, my colleague, and I were very conservative in our approach to building the cost estimates. We only went to those supplements that had the most strong scientific evidence, and when we did our costing, we only looked at a few of the possible areas where cost savings might exist.

As Dr. Coates has indicated, for instance, for calcium, there is many areas where it will be effective, but we only looked at a few specific areas where the evidence was strongest. That is to say for calcium, we estimated savings for avoided hip fractures for over age 65; and for folic acid, we looked at avoided incidences of babies being born with neural tube defects.

In terms of our key findings for calcium, for a daily intake of 1,200 milligrams of calcium D, calcium with vitamin D, could result in 734,000 fewer hip fractures for the population aged 65 and over. We estimated that would save about $13.9 billion over a 5-year period. We used the CBO-type scoring procedures, which you are familiar with, because CBO scores all of our budgetary items for you. We tried to use their procedures because they are well known and fairly conservative in their approach, and subject to

much scrutiny, and we feel that those kinds of procedures are the appropriate ones to use.

We looked at net savings in hospital, nursing facility and physician expenditures. There again, we could have added more expenditures to the list, but we felt we would take the biggest ones and the least controversial with respect to hip fractures.

Over one-third of adults over age 65 experience falls each year. Hip fractures caused the most severe health problems and the greatest number of deaths. So not only are we looking at cost savings here, we are looking at improved health and people's status in terms of feeling better. When you have a broken hip and you are over 65, it is not a good condition to be in. If we can avoid that, not only do we save money, but we improve people's health status enormously.

In terms of folic acid, there are 64 million women of child-bearing years in the United States. Again, we were conservative, and we said if an additional 10.5 million, or 25 percent of those not currently taking folic acid, begin to take 400 micrograms of folic acid on a daily basis, we estimated that 600 babies would be born without neural tube defects. Our savings over 5 years, using the CBO estimates again, were about $1.3 billion. Again, these are conservative, because we only took 25 percent.

The problem here is not so much the effects of the supplement itself, but getting people to take the supplements. And the recommendation here, of course, would be that we do a lot as a society, much more as a society, to get people to understand both the benefits of taking the supplement and the risk of not taking it, which are enormous.

For omega–3 fatty acids, we found that there was a lot of evidence. As we heard from Dr. Coates, a lot of it is good. But the evidence wasn't quite strong enough to do our cost estimates. And as Dr. Coates indicated, the government is under way taking studies where perhaps we will have stronger evidence in the future.

Similarly with glucosamine and saw palmetto, we found that the evidence was strong, it was encouraging, but it wasn't quite up to the rigor that we would like before we did our cost studies. So for those two studies, we note that the government is undertaking again, and already under way, very large double-blind, placebo controlled studies, which should provide us the evidence in the future with which we can proceed with cost studies.

In closing, I would like to note that the typical American diet does not always provide a sufficient level of nutrients to support optimal health, very much as you said in your introductory comments, and then that would be the overall conclusion of this; that is, in certain instances, supplements are an inexpensive and safe way to improve health status and reduce health care expenditures, and in these cases the role of public policy to support their use is unambiguous.

I would thank you for the opportunity to present these findings from the Lewin Group study. Thank you.

Mr. BURTON. Thank you, Doctor.

[The prepared statement of Mr. Dobson follows:]

Statement by:

Al Dobson, Ph.D.
The Lewin Group
Falls Church, Virginia

Before the

Committee on Government Reform
U.S. House of Representatives

Regarding:

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

Date:

September 22, 2004

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 Nueral 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 artherosclerosis, and may reduce the risk associated with irregular heartbeats. However, at this time the specific effects on different cardiovascular disease outcomes (especially miocardial 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.

Improving Public Health, Reducing Health Care Costs: An Evidence-Based Study of Five Dietary Supplements

Fact Sheet

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. Some individuals may need a vitamin and/or mineral or other supplement to meet specific nutrient needs.[1]

The Lewin Group, Inc. was commissioned by the Dietary Supplement Education Alliance (DSEA) to conduct an evidence-based study of five dietary supplements. The purpose of this study is threefold: (1) to critically review the research literature for consistency, validity (closeness to the truth), and impact (size of the effect), (2) to develop estimates of the potential health care expenditure savings that could result from daily use of two of the supplements, and (3) for supplements where there is emerging evidence, to suggest areas of future research that would fill existing knowledge gaps. 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**.

Lewin was asked to develop estimates of potential cost savings that could result from daily use of 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. Cost estimates were developed for calcium (with Vitamin D) and folic acid, for which there is significant scientific agreement as to the improvement in health status and subsequent health expenditure reduction.

Key Study Findings

- **Calcium:** Using a Congressional Budget Office (CBO-type) cost accounting methodology, the estimate of 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 over age-65 population through daily intake of 1200 mgs. of calcium with Vitamin D is $13.9 billion. Approximately 734,000 hip fractures could be avoided across the five years. See Table 1 below.

- **Folic acid**: The total lifetime cost of a baby with Neural Tube Defect (NTD) in 2004 is roughly $532,000, including direct medical costs, therapies and equipment, and special education. Out of about 4 million live births annually, NTDs occur in one of every 1,000 pregnancies in the U.S.[2] Of 64 million American women who are of childbearing age, if just 10.5 million additional women began taking 400 mcg. of folic acid on a daily basis periconceptionally, approximately 600 babies would be born without NTDs, saving as much as $321,853,000 as a result. Over five years, taking into account the very low cost of the supplement, $1.3 billion in lifetime costs could potentially be saved. Longstanding and extensive research with supporting conclusions led the US Public Health Service, Institute of Medicine, and Food and Drug

[1] US Department of Agriculture, US Department of Health and Human Services. (2000). *Dietary Guidelines for Americans.* Washington DC.

[2] Spina Bifida Association of America. Spina Bifida – The Facts. Available at: http://www.sbaa.org. Accessed April 24, 2004.

Administration (FDA) to establish recommendations and public health policies relating to folic acid intake and food fortification.[3] See Table 2 below.

Table 1: Costs and Potential Savings Resulting From Reduced Hip Fractures

	2005	2006	2007	2008	2009	Total
Total cost of daily calcium for new users (adults over 65 not currently taking calcium) and current users paid for by payer over time	$575	$714	$833	$957	$1,071	$4,149
Cost offset due to avoided hospitalizations, physician services, and SNF stays associated with reduced hip fractures for population most at risk	$3,076	$3,231	$3,393	$3,561	$3,737	$16,988
Net cost of daily calcium for adults over 65	-$2,645	-$2,696	-$2,768	-$2,843	-$2,934	-$12,849
Premium offset (25% of additional program spending)	$144	$178	$208	$239	$268	$1,037
Total potential cost offset from avoided health care utilization associated with avoided hip fracture (savings)	$2,646	$2,696	$2,768	$2,843	$2,934	$13,886

Table 2: Costs and Potential Savings Resulting From Fewer Cases of NTD

	2005	2006	2007	2008	2009	Total
Annual Per Person Cost of Daily Folic Acid Supplement for Women of Childbearing Age	$7.04	$7.22	$7.40	$7.58	$7.58	
Number of New Users of Folic Acid (in millions)	10.8	11.0	11.0	10.9	10.6	
Gross Cost of Daily Folic Acid Supplement for New Users among Women of Childbearing Age (in millions)	$76.3	$79.4	$81.6	$82.6	$82.5	$402.4
Total Lifetime Cost of NTD per Case (in thousands)	$543	$558	$572	$587	$599	
Number of New Cases per Year	4,100	4,202	4,308	4,415	4,503	21,528
Annual Lifetime Cost of New Cases of NTD (in billions)	$2.2	$2.3	$2.5	$2.6	$2.7	$12.3
Total Savings associated with 600 Fewer NTD Cases (in millions)	$326	$335	$344	$352	$359	$1,717
Net Savings of Providing 10 Million Women with Daily Folic Acid (savings) (in millions)	$250	$256	$262	$270	$264	$1,315

- **Omega-3 fatty acids**: Recent studies have shown that omega-3 fatty acids can have beneficial effects on cardiovascular disease (CVD). Furthermore, FDA recently announced a qualified health claim for EPA and DHA omega-3 fatty acids.[4] The research literature contains many promising studies of varying quality concerning the health benefits of omega-3 fatty acids for a wide number of chronic conditions (e.g., depression, renal disease, rheumatoid arthritis, and asthma) and additional research is warranted to verify these preliminary suggestions.[5] Our

[3] Bailey L, Rampersaud G, Kauwell G. Folic Acid Supplements and Fortification Affect the Risk for Neural Tube Defects, Vascular Disease and Cancer: Evolving Science. *Journal of Nutrition.* 2003;133: 1961S-1968S.

[4] USDHHS: FDA. FDA Announces Qualified Health Claims for Omega-3 Fatty Acids. *FDA News –Sept 8, 2004.*

[5] Holub, Bruce J., "Clinical Nutrition 4. Omega-3 Fatty Acids in Cardiovascular Care". *JAMC*, 2002; 166(5) 608-615.

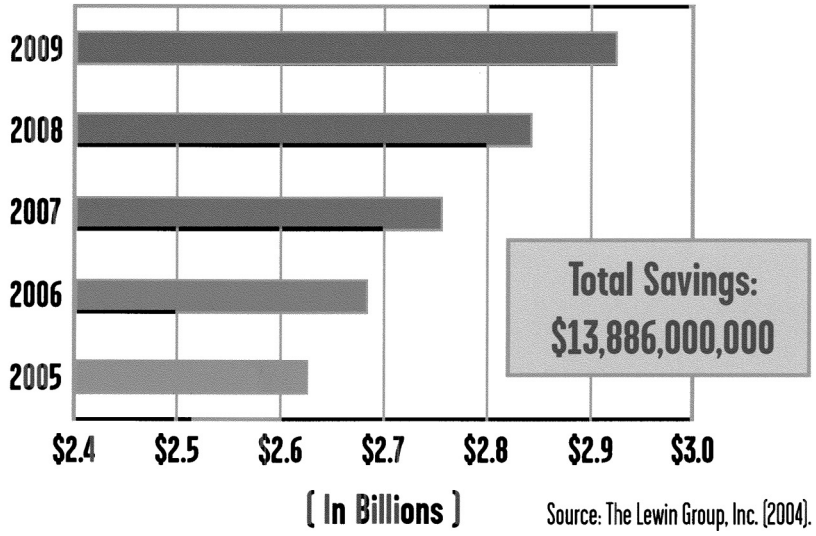
review found consistent evidence that omega-3 fatty acids help reduce deaths from CVD. In addition, there are studies demonstrating that omega-3 fatty acids may help lower blood pressure, may reduce the risk of re-blockage after an angioplasty, may increase exercise capacity in people with coronary atherosclerosis, and may reduce the risk associated with irregular heartbeats. In March 2004, the Agency for Healthcare Research and Quality (AHRQ) commissioned a systematic review of the literature to assess the benefits of omega-3 fatty acids on CVD outcomes. [6] AHRQ found that studies of omega-3 fatty acids were heterogeneous in that they examined different forms of omega-3 fatty acids. AHRQ concluded that focused and well- designed multicenter RCTs are now needed to validate earlier promising results and fill in any knowledge gaps.

- **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. Osteoarthritis is the most common musculoskeletal disease in the world, and its actual cause remains unknown. In 1999, approximately 10 million adults reported being diagnosed with osteoarthritis. The use of complementary and alternative therapies in the treatment of osteoarthritis has become more widespread, and particular interest has focused on glucosamine.[6]

- **Saw Palmetto:** Preliminary findings 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. A recently released review of clinical trials of the herb also found that saw palmetto reduces the symptoms of BPH, increases urinary flow, improves the quality of life and is well tolerated, and may be considered a viable first-line therapy for treating lower urinary tract symptoms associated with BPH.[7] Additionally, at this time there are no known safety hazards or contraindications to using saw palmetto with other medications. 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 (e.g., the influence of confounding variables on observed outcomes.)

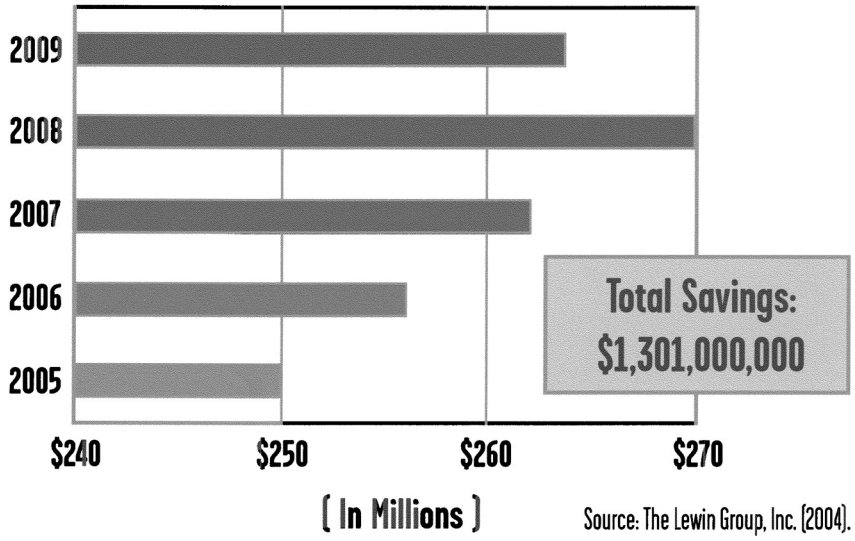
[6] http://clinicaltrials.gov/ct/gui/c/w1b/show/NCT0003715 accessed August 2, 2004.
[7] Gerber GS, Fitzpatrick JM. (2004). The role of a lipido-sterolic extract of Serenoa repens in the management of lower urinary tract symptoms associated with benign prostatic hyperplasia. *BJU;* 94(3) August: 338-344.

Net Savings Resulting from Reduced Hip Fractures Among Adults Over Age 65 Taking Daily Calcium Supplements



Source: The Lewin Group, Inc. (2004).

Net Savings Resulting from Reduced Neural Tube Defects Among 10 Million Women Taking Daily Folic Acid Supplements



Source: The Lewin Group, Inc. (2004).

Calcium

Introduction

Calcium is the most abundant mineral in the human body. Average healthy males have about two and a half to three pounds of calcium while females have about two pounds. Approximately 99 percent of calcium is present in the bones and teeth, which leaves only about one percent in cells and body fluids. While the most important function of calcium involves the maintenance of skeletal health, the small percentage of calcium outside the bones is used to maintain a variety of vital body functions.

Milk and dairy products are the major source of dietary calcium for most people. Other good sources are dark green leafy vegetables, broccoli, legumes, nuts, and whole grains.

Reported Uses

As most people know, calcium is crucial for the development and long-term health of bones and teeth. The body's need for calcium is greatest during periods of rapid growth including childhood, pregnancy, and lactation.

Calcium is also necessary for a wide array of other functions. Calcium may initiate muscle contractions. For this reason it plays a vital role in maintaining a healthy heartbeat. It is also involved in the body's blood clotting process. On the cellular level, calcium regulates the passage of nutrients and wastes through cell membranes. It is also involved in the regulation of various enzymes that control muscle contraction, fat digestion, and metabolism. Finally, calcium regulates the transmission of nerve impulses.

Calcium has received much attention for its role in supporting bone health in postmenopausal women. Research suggests that calcium can slow the progression of osteoporosis. Calcium's importance for maintaining strong, healthy bones and slowing bone loss cannot be overstated. Studies have suggested that during perimenopause, calcium absorption decreases and thus calcium supplements are a prudent dietary measure during menopause. Various types and dosage forms of calcium have been shown to delay bone loss in postmenopausal women.

There are several other targeted applications for calcium. For instance, it may be involved in blood pressure regulation. Studies have suggested that low levels of calcium are associated with high blood pressure. Studies also suggest that it may also aid in the prevention of colorectal cancer in men. What's more, calcium supplementation may reduce cholesterol levels.

By reducing stone formation, calcium supplementation has shown promise in the treatment of kidney stones. For support of PMS, calcium may dramatically reduce symptoms. Calcium taken after the 20th week of pregnancy may also reduce a woman's risk of pregnancy-related hypertension.

Source: Dietary Supplement Education Alliance

Folic Acid

Introduction

Folic acid is a member of the water-soluble B vitamin group. Isolated in 1946 from spinach leaves, its name comes from *folium*, the Latin word for leaf. In the body, folic acid is converted to a more biologically active form.

Folic acid occurs in a wide variety of foods. Best sources include dark green leafy vegetables, brewer's yeast, liver, and eggs. Other good sources are beets, broccoli, brussels sprouts, orange juice, cabbage, cauliflower, cantaloupe, kidney and lima beans, wheat germ, and whole grain cereals and breads. The body's "friendly" intestinal bacteria also produce folic acid.

Reported Uses

Like vitamin B_{12}, folic acid is necessary for the production of both DNA and RNA. It is therefore essential for proper cellular division and the transmission of the genetic code to all newly formed cells. It is also essential for the health of red blood cells and the production of proteins and various amino acids.

In women, folic acid is crucial for closure of the fetus' neural tube during pregnancy. This makes adequate folic acid levels essential for preventing neural tube birth defects such as spina bifida. In general, pregnancy increases a woman's requirements for folic acid. Women with higher intakes of folic acid may have a reduced risk of ovarian cancer. Also, of importance to women, folic acid may treat cervical dysplasia and decrease the necessity of hysterectomies.

Studies also suggest that many people with major depression or schizophrenia may benefit from folic acid supplementation. Benefit may also be extended to alcoholics, who are commonly deficient in folic acid. One form of anemia that arises from folic acid deficiency can also be reversed with supplementation.

Studies have shown cognitive skills such as knowing, thinking, learning, and judging can be impaired in older adults with low levels of certain B vitamins. Supplementation with folate, vitamin B12, and vitamin B6 has been effective in enhancing cognitive performance in older adults. In fact, studies in older adults noted that subjects with low levels of vitamin B12 or folate had more of a risk of developing Alzheimer's disease.

Folic acid can also lower homocysteine levels, even when the levels are increased by lipid lowering medications. Because homocysteine is an amino acid that is a significant risk factor for atheroslerosis, folic acid may prevent the development and progression of the disease. Hemodialysis patients were treated with B-vitamins and folic acid which significantly lowered homocysteine levels. Dietary supplementation with the B-vitamins prevented hyperhomocysteinemia but did not prevent the development of vascular dysfunction or atherosclerotic lesions. Other studies involving hundreds of patients who had undergone successful coronary angioplasty have evaluated these individuals following six months of therapy on vitamin B6, vitamin B12, and folic acid, comparing the results to patients on placebo. After one year, the patients on the vitamin therapy had lower rates of related cardiovascular events including heart attacks and repeated angioplasty. Homocysteine can also interfere with normal bone structure, folic acid's homocysteine-lowering function may also be of benefit in the prevention of osteoporosis.

Source: Dietary Supplement Education Alliance

Omega-3 Fatty Acids

Introduction

In the late 1970s, scientists learned that those who consumed a diet very high in omega-3 fatty acids had surprisingly low rates of heart attacks. Since that time thousands of scientific studies have evaluated the multiple ways that omega-3 fatty acids promote not only cardiovascular health, but also the healthy functioning of many other biological activities. Many Americans don't get enough of it in their diets. One reason is that omega-3 oils are very susceptible to spoilage and so many food manufacturers remove it to keep products fresh. Another reason is that omega-3 oils mostly come from cold water fish and wild game-- something most Americans don't eat in great quantities.

Flaxseed oil is another good source of omega-3. Other sources include chia, rapeseed, soybeans, alfalfa and walnuts. In most cases, however, people are not able to consume adequate amounts of omega-3 from dietary sources, and physicians often recommend supplementation.

Omega-3 refers to a group or "family" of unsaturated fatty acids. The first fatty acid in this group is named alpha linolenic acid or just linolenic acid, and sometimes it is just called omega-3. Linolenic acid cannot be made in the body and therefore, it is classified as an essential fatty acid and must be obtained from either the diet or in supplement form. The other two fatty acids in the omega-3 family are named eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The body can manufacture EPA and DHA by conversions from linolenic acid.

Reported Uses

Omega-3 fatty acids are one of the primary structural components in cell walls and membranes throughout the body. They are also instrumental in regulating inflammation, blood pressure and thickness, hormone production, and the activities of the immune and central nervous systems. Omega-3 fatty acids are important for infants (and a developing fetus) for proper development of the brain and retina of the eyes.

There are many clinical applications for omega-3. Omega-3 fatty acids can support cardiovascular health by lowering blood pressure, relaxing blood vessels and lowering cholesterol levels. Dietary intake of omega-3 fatty acids reduced inflammation and endothelial activation, which may help prevent cardiovascular disease. Taking 3 to 5 grams of omega-3 fatty acids per day can decrease elevated serum triglycerides as much as 50%. Results of a recent study in Italy reported that patients taking 850 milligrams per day of omega-3 fatty acids had a lower rate of death related to heart conditions than those who were not taking the fatty acid.

Studies suggest that Attention Deficit Hyperactivity Disorder (ADHD) may be linked to omega-3 deficiency. Deficiencies have also been found in people who have allergies, asthma, and skin disorders like eczema and psoriasis.

Omega-3 may also be a preventative measure for many major illnesses. Researchers think omega-3 can help prevent breast, prostate, and colon cancers. Postoperative cancer patients supplemented with omega-3 experienced improved liver and pancreas function. New preliminary research shows that omega 3 could be beneficial for cystic fibrosis, type 2 diabetes, and inflammatory bowel disease.

Omega-3 may also decrease inflammation and reduce pain for sufferers of rheumatoid arthritis. Deficiencies of omega-3 in the United States as well as other countries may also be linked to depression. Omega 3 has also shown possible beneficial effects for other mental disorders as well.

Source: Dietary Supplement Education Alliance

GLUCOSAMINE

Introduction

Glucosamine is a precursor for substances that provide the foundation for many of the body's tissues including tendons, ligaments, cartilage, collagen, and more. What's more, glucosamine supports the health of tissues that make up many of the body's organs.

Glucosamine does not occur in foods. Supplemental sources of glucosamine are derived from the processed exoskeleton of shrimp, lobster, and crab shells.

Reported Uses

Glucosamine has another, related benefit in addition to supporting health of joints and tissues. It also functions as an anti-inflammatory. Studies that have looked at glucosamine's anti-inflammatory properties have suggested that it may treat two common types of arthritis, gonarthritis and osteoarthritis. Studies noted not only symptomatic improvement in patients with knee osteoarthritis but also the arthritis did not progress as rapidly as it did in the placebo group. Another study indicates that the combination of glucosamine, chondroitin sulfate and manganese ascorbate was more effective at slowing the progression of cartilage breakdown than any of these agents alone.

Glucosamine has also been used to treat kidney stones and the joint noises and pain associated with temporomandibular joint dysfunction (TMJ). Finally, glucosamine may promote faster healing and lessen scarring from wounds or surgery.

SAW PALMETTO

Introduction

Many middle age men contend with benign enlargement of the prostate. While conventional drugs can offer treatment of the disorder, one natural remedy, saw palmetto, may rival them in effectiveness. A standardized extract is derived from the berry of the saw palmetto.

Reported Uses

Benign enlargement of the prostate is thought to be caused by chain of interactions involving the conversion of testosterone into another form within the prostate gland. Scientists think the key compounds present in saw palmetto may help circumvent this process. Patients pretreated with saw palmetto undergoing a prostate operation seemed to experience a reduced risk of complications in comparison to the control group.

Scientists also believe prostate enlargement may in part be related to the presence of estrogen in the prostate. It is believed that saw palmetto can help the male body dispose of this excess estrogen.

In addition to its support of prostate health, the non-extracted berry of the saw palmetto may support healthy function of the immune system.

Source: Dietary Supplement Education Alliance

Mr. BURTON. We didn't get into any other—they only asked you about those five products?

Mr. DOBSON. Yes.

Mr. BURTON. Didn't get into vitamin C or any of the others?

Mr. DOBSON. No. We took the five—we knew there was a great deal of literature out there, and we wanted to look at those cases where we thought we had the best case to move beyond the studies of efficacy and impact on health and move into cost savings. So we felt that we would look at those where the literature in come cases is 30 and 40 years in length.

Mr. BURTON. OK.

Dr. Blumberg.

Mr. BLUMBERG. Good morning. I am a professor of nutrition at the Friedman School of Nutrition Science and Policy, and the associate director of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University in Boston. I also serve as a nonpaid member of the Scientific Advisory Board of the Dietary Supplement Education Alliance. I have been investigating the role of dietary supplements in the promotion of health and prevention of chronic disease for almost 25 years.

It is now indisputable that nutrition is a key component of any disease-prevention strategy, and optimal intakes of vitamins, minerals, and other nutrients are critical to maintaining wellness. Virtually every nutrition-monitoring survey reveals that most Americans fail to achieve these intakes through their usual diets. Fortunately, dietary supplements represent an affordable, effective and practical tool to help solve this problem, and thus ultimately reduce health care costs.

This morning I will illustrate this principle with the example of folic acid. Folic acid is a B vitamin essential to the activity of more than a dozen enzymes, amino acid metabolism, and DNA formation. Inadequate intake of folic acid has been associated with anemia, some forms of cancer, heart disease, poor pregnancy outcomes, and birth defects, most notably neural tube defects, but also including cleft lip and palate, limb deficiencies and defects of the heart.

The richest dietary sources of folic acid are liver, mushrooms, dried beans, green leafy vegetables, and, since 1998, enriched grains fortified with this vitamin.

The recommended dietary allowance for folic acid is 400 micrograms daily. Usual intakes of folic acid before fortification were 200 micrograms, but are now estimated to be about 300 micrograms, with much lower intakes in people following low-carbohydrate diets and avoiding fortified breads and other cereals.

However, it is important to understand that many people have a greater need for folic acid, including pregnant and lactating women, people who consume alcoholic beverages or take certain medications, patients with certain inflammatory conditions of the intestines, and the elderly.

For the last 5 years, the Center for Disease Control and Prevention and the Institute of Medicine have recommended that all women capable of becoming pregnant should consume 400 micrograms per day of synthetic folic acid from supplements or fortified foods, in addition to consuming food folate from a variety of dietary sources. Nonetheless, two-thirds of American women of

child-bearing age do not follow this advice, and 1 of every 1,000 babies in the United States is born with a neural tube defect.

The Lewin Group analysis which you just heard about calculated that over the next 5 years, $1.3 billion in health care costs could be saved if these women took a daily supplement containing 400 micrograms of folic acid, but folic acid supplements are not just for women. Observational studies consistently reveal that men and women taking supplements containing folic acid have the lowest blood levels of the amino acid homocysteine. Elevated levels of homocysteine are a significant independent risk factor for atherosclerotic vascular disease and for thromboembolism. Some evidence suggests that lowering homocysteine levels could reduce the risk of heart disease by 20 percent. Many studies reveal that elevated homocysteine may enhance the effect of other established vascular risk factors such as hypertension and smoking.

Folate inadequacy also has a procarcinogenic effect by interfering with normal DNA synthesis and regulation. An increased risk for some forms of cancer has been associated with poor folate status in several epidemiological studies, with the strong evidence linked to colorectal cancer.

Studies have also suggested that the increased risk of breast cancer associated with regular alcohol consumption may be reduced by an increased intake of folic acid from dietary supplements.

While many different factors contribute to the risk of poor health and chronic disease, we know that diet and the intake of specific nutrients play a key role in the prevention of cancer, diabetes, heart disease, infectious diseases, macular degeneration, osteoporosis and other conditions.

The power of nutrition to promote health is well established. We need now to find ways to encourage Americans to choose helpful dietary patterns and increase their intake of key nutrients with fortified foods and dietary supplements. If we succeed in doing so, both the personal burden of disease carried by Americans and the associated enormous expenditure for their health care will be substantially reduced. Thank you.

Mr. BURTON. Thank you, Dr. Blumberg.

[The prepared statement of Mr. Blumberg follows:]

Jean Mayer
United States Department of Agriculture
Human Nutrition Research Center on Aging
At Tufts University

Committee on Government Reform
Subcommittee on Human Rights and Wellness
Representative Dan Burton, Chairman

September 22, 2004
Rayburn Building, Washington, DC

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

Testimony by:

Jeffrey B. Blumberg, PhD, FACN, CNS
Friedman School of Nutrition Science and Policy
Jean Mayer USDA Human Nutrition Research Center on Aging
Tufts University
Boston, MA

The Role of Folic Acid and Other Dietary Supplements in the Promotion of Health and Prevention of Chronic Disease

I am a Professor of Nutrition at the Friedman School of Nutrition Science and Policy and the Associate Director of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University. I also serve as a non-paid member of the Scientific Advisory Board of the Dietary Supplement Education Alliance. I have been investigating the role of dietary supplements in the promotion of health and prevention of chronic disease for almost 25 years. It is now indisputable that nutrition is a key component of any disease prevention strategy and optimal intakes of vitamins, minerals and other nutrients are critical to maintaining wellness. Virtually every nutrition-monitoring survey reveals that most Americans fail to achieve these intakes through their usual diets. Fortunately, dietary supplements represent an affordable, effective, and practical tool to help solve this problem and, thus, ultimately reduce healthcare costs. While I will illustrate this principle with the example folic acid, it is important to recognize there is an extensive body of scientific evidence demonstrating the health benefits of other dietary supplements as you are hearing from other experts today.

Folic acid is a B vitamin essential to the activity of more than a dozen enzymes, amino acid metabolism, and DNA formation. Inadequate intake of folic acid has been associated with anemia, some forms of cancer, heart disease, poor pregnancy outcomes

(including preterm delivery, infant low birth weight, fetal growth retardation), and birth defects, most notably, neural tube defects (NTD) leading to spina bifida and anencephaly but also including cleft lip and palate, limb deficiencies, conotruncal defects of the heart, and Down syndrome. The richest dietary sources of folic acid are liver, mushrooms dried beans, green leafy vegetables, and since 1998, enriched grains fortified with this vitamin. The Recommended Dietary Allowance for folic acid is 400 μg daily. Usual intakes of folic acid before fortification were 200 μg but are now estimated to be about 300 μg with much lower intakes in people following low carbohydrate diets and avoiding fortified breads and other cereals. However, it is important to understand that many people have a greater need for folic acid, including pregnant and lactating women, people who consume alcoholic beverages or take certain medications (e.g., aspirin, methotrexate, pyrimethamine, trimethoprim), patients with certain inflammatory conditions of the intestine (e.g., enteritis with malabsorption such as sprue), and the elderly.

For the last five years, Center for Disease Control and Prevention and the Institute of Medicine has recommended that all women capable of becoming pregnant should consume 400 μg/day of synthetic folic acid from supplements or fortified food in addition to consuming food folate from a variety of dietary sources. The scientific basis of this recommendation included data from population-based studies and randomized clinical trials as well as extensive experimental studies. Folic acid supplements have been proven to be the most effective and reliable method to reduce the probability of NTD. Nonetheless, two-thirds of American women of child-bearing age do not follow this advice and one of every thousand babies in the US is born with an NTD. The Lewin Group analysis calculated that over the next five years $1.3 billion in health care costs could be saved if these women took a daily supplement containing 400 μg folic acid.

But folic acid supplements are not just for women. The benefits of daily folic acid supplementation extend well beyond reducing the risk of NTD and other birth defects. Observational studies consistently reveal that men and women taking supplements containing folic acid have the lowest blood levels of the amino acid homocysteine. Some evidence suggests that lowering homocysteine levels could reduce the risk of heart disease by 20 percent. Elevated levels of homocysteine are a significant, independent risk factor for atherosclerotic vascular disease in the coronary, cerebral, and peripheral vessels and for arterial and venous thromboembolism. Many studies reveal that elevated homocysteine may enhance the effect of other established vascular risk factors such as hypertension and smoking. Low intakes of folic acid have now been shown to be the primary determinant of mild-to-moderate elevations of homocysteine. Randomized clinical trials investigating the effect of folic acid supplements on risk of heart disease, stroke, and dementia are now being supported with Federal funds.

Folate inadequacy has a pro-carcinogenic effect by interfering with normal DNA synthesis and regulation (via methylation reactions). An increased risk for some forms of cancer has been associated with poor folate status in several epidemiological studies, with the strongest evidence linked to colorectal cancer. However, studies have also suggested that the increased risk of breast cancer associated with regular alcohol consumption may be reduced by an increased intake of folic acid from dietary supplements. Recent

experimental research has shown that low consumption of folic acid impairs the integrity of the genome, particularly tumor suppressor genes, and this effect can be reversed by supplementing the diet with folic acid.

While many different factors contribute to the risk of poor health and chronic disease, we know that diet and the intake of specific nutrients play a key role in the prevention of cancer, diabetes, heart disease, infectious diseases, macular degeneration, osteoporosis, and other conditions. The power of nutrition to promote health is well established. We need now to find ways to encourage Americans to choose healthful dietary patterns and increase their intake of key nutrients with fortified foods and dietary supplements. If we succeed in doing so, both the personal burden of disease carried by Americans and the associated enormous expenditure for their healthcare will be substantially reduced.

Thank you.

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Submitted by:

Jeffrey Blumberg, PhD, FACN, CNS
Associate Director and Professor

Friedman School of Nutrition Science and Policy
Jean Mayer USDA Human Nutrition Research Center on Aging
Tufts University
711 Washington Street
Boston, MA 02111

tel: 617-556-3334
Fax: 617-556-3295
EM: jeffrey.blumberg@tufts.edu

Mr. BURTON. Dr. Levine.

Ms. LEVINE. Good morning, Chairman Burton. I am Barbara Levine, associate professor of medicine at Weill Cornell Medical College, as well as the head of clinical nutrition at Strang, which is part of Cornell Medical College, as well as the Rockefeller University.

It is a great honor to be able to address you about the importance of the nutritional health of Americans. More specifically, I will be discussing two nutrients I have studied for most of my career. The first nutrient is calcium, which is found in every cell of the body. Calcium is essential for bone development and growth, and in the protection of the human body through all stages of life.

Prolonged low calcium intake has been linked to the development of several chronic diseases, including colon cancer, hypertension and osteoporosis, and we have to remember that we reach our peak bone mass really at around age 20, and then bone resorption will really exceed bone formation, so that it is very important for us to get enough calcium very early on in life, but continue to get the calcium we need throughout our life so that we don't lose more bone than we make.

It is generally accepted that the ideal method for obtaining calcium is through regular dietary sources. Unfortunately, meeting the recommended daily intake of calcium has proven to be difficult for the average American, as evidenced by the low percentage of individuals actually meeting recommended calcium intake levels on a continuing daily basis.

In the recent National Health and Nutrition Examination Survey, it was reported that the average intake of calcium for women, for example, age 40 and over, was only 698 milligrams per day. This is well blow the 1,200-milligrams-per-day calcium intake recommended for postmenopausal women, and illustrates the overall need to encourage calcium supplementation.

And this is true for men as well, as we know that women generally experience fractures earlier on because of postmenopause, but men catch up in the sixth decade of life and will experience hip fractures as well.

Not only can calcium supplements help to increase the intake of calcium among our population, but also the resultant disease prevention can help cut health care costs substantially.

The second nutrient I will discuss today is actually part of a group of nutritional components, the much-heralded omega–3 fatty acids. This group has a major role in the maintenance of cardiovascular health, development of the nervous system and other key functions. As was mentioned today, there is more evidence in the secondary prevention of the omega–3 fatty acids, which include DHA, docosahexaenoic acid, and eicosapentaenoic acid.

But we just finished, and I will have the results at the Rockefeller University, a primary prevention study with DHA in patients that are overweight and have the syndrome called metabolic syndrome. So they are overweight, they have high triglycerides, they generally have insulin resistance, and we will get you that information as soon as possible.

But the role of omega–3 fatty acids and cardiovascular function has been studied for the last 40 years. I would like to commend the

American Heart Association for its recent Scientific Statement on Fish Consumption, Fish Oil, Omega–3 Fatty Acids and Cardiovascular Disease. This statement confirms the importance of long-chain omega–3 fatty acids, both DHA and EPA, for their significant role in the reduction of cardiac death. DHA recommends that patients with coronary disease and hypertriglyceridemic patients, that is with the high triglycerides, consume DHA and EPA as part of their medical management.

As just another example of the importance of omega–3 fatty acids, research has found that DHA is particularly vital for pregnant and lactating women because it plays a critical role in supporting brain and retinal development in infants. A recent workshop supported by NIH recommends 300 milligrams of DHA a day for pregnant and nursing women to promote optimum neurological development and visual acuity in their babies.

As I mentioned in my discussion of calcium, despite our best intentions, the nutritional health of our Nation remains suboptimal. The principal dietary source of omega–3 fatty acids is coldwater fish like salmon and trout. However, both the United States Food and Drug Administration and the Environmental Protection Agency has recently scrutinized certain fish, such as shark, swordfish and fresh frozen tuna, for having potentially high levels of methyl mercury. And the Heart Association tempers its recommendations to increase DHA and EPA intake by stating that the availability of high-quality omega–3 fatty acid supplements, free of contaminants, is an important prerequisite to their extensive use. This is even more important for pregnant and lactating women who would benefit from DHA. These are a clear example of the benefits of supplementation which can provide high-quality omega–3 without contamination.

I thank you for the opportunity to speak to you about these important nutrition issues. Thank you, Mr. Chairman.

Mr. BURTON. Thank you.

[The prepared statement of Ms. Levine follows:]

TESTIMONY OF BARBARA LEVINE
BEFORE
THE COMMITTEE ON GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES
September 22, 2004

Mr. Chairman and members of the Committee, I am Dr. Barbara Levine, Associate Professor of Nutrition in Medicine, Weill College of Medicine of Cornell University. I also serve as a non-paid member of the Scientific Advisory Board of the Dietary Supplement Education Alliance. It is a great honor to be able to address you today about the importance of the nutritional health of Americans. More specifically, I will be discussing two nutrients I have studied for most of my career.

The first nutrient is actually part of a group of nutritional components – the much-heralded omega-3 fatty acids. These include DHA (docosahexaenoic acid) that has a major role in the development of the central nervous system. DHA, together with EPA (eicosapentaenoic acid), is also very important to maintaining cardiovascular health. EPA also is responsible for suppression of immune function. The second nutrient is calcium, found in every cell of the body and is so important to numerous biological functions. Calcium is essential for bone development and growth, and in the protection of the human body through all stages of life.[1]

These two nutrients have a common thread. They are essential from the very beginning of life – and even before -- because a woman needs to be replete in these nutrients before entering pregnancy to ensure that the fetus will derive what is essential for proper growth and development from the mother. And they are also essential to maintaining the mother's health and a successful outcome in the birth of her child. Thus, these two nutrients are needed throughout the entire life cycle in the development and growth of the human body as well as for prevention and treatment of a variety of diseases that occur during life.
One would have assumed that, living as we do in the richest country in the world, that our diet would also be rich in these nutrients. Yet the reality is that despite our best intentions, the nutritional health of our nation remains sub-optimal. Our whole way of eating has come very far from the original hunter-gatherers who were able to fulfill their need for calcium and DHA through their diet of meat, grains, nuts and berries and other dietary sources. The obesity epidemic for both adults and children is on the rise. Notwithstanding the role of genetics and economic status, this epidemic is largely due to less physical exercise, eating less healthful foods and eating larger portions. Because childhood obesity is likely to persist into adulthood, the American Academy of Pediatrics recently published a policy statement on Prevention of Pediatric Overweight and Obesity, which addresses the recognized risk factors.[2]

Omega-3's
The role of omega-3 fatty acids in cardiovascular function has been studied for the last 40 years. As we are learning more about the three primary omega-3 fatty acids (linolenic acid, LNA; eicosapentaenoic acid, EPA; and docosahexaenoic acid, DHA), it is becoming clear that each of these fatty acids have different functions in the body. For example, DHA is primarily involved in central nervous system function, EPA is responsible for blood thinning and suppression of immune function, and LNA is a precursor molecule that, by itself, has little or no effect. Although a general triglyceride lowering effect has been reported with fish oil (fish oils contain both EPA and DHA), it has only recently become clear which omega-3 fatty acid is responsible for this effect.

DHA and Infant Development
Over the past 20 years, there has been a dramatic increase in the scientific scrutiny of the essential polyunsaturated fatty acid, DHA, and its impact on health. While DHA is important for all people at all stages of life, optimum amounts of DHA are particularly vital for pregnant and lactating women. To acquire appropriate levels of fatty acids, nursing newborns rely upon the mother's store of DHA, which, in the United States, is usually insufficient. If adequate amounts of DHA are not transferred from the nursing mother's blood via the placenta, the newborn's brain, nervous system, and eye function may not reach their peak development.

One of the most significant areas of research on DHA involves infant brain development. DHA plays a critical role in supporting brain and retina development in infants. A mother provides DHA to her baby *in-utero* and via breast milk. Throughout pregnancy, a developing fetus will receive DHA from the mother, particularly during the last trimester when there is significant brain growth. The human brain grows at a rapid pace during this late stage of fetal development; and the DHA content of the fetal brain increases three to five times during the final trimester of pregnancy and triples during the first twelve weeks of life. In addition, the retina, which is rich in DHA, develops rapidly during the final months of pregnancy and the first six months of infancy. Preterm infants run the greatest risk of vision problems because they miss the final weeks of gestation when the retina concentrates DHA.

For an assortment of reasons, the average American diet lacks adequate amounts of DHA. Historically, human beings have, up until recently, consumed large amounts of fish, game and organ meats (all sources of DHA). In the past 100 years or so, our intake of these foods has decreased dramatically. In fact, the typical American diet contains less than 100mg DHA a day. Scientists are concerned that pregnant women in particular are not getting enough of this vital omega-3 in their diets.

The principal dietary source of DHA is cold-water fish, like salmon and trout, foods that are not consumed in great amounts by American women. The purest

source of DHA is not the fish itself, but rather what fish consume: the ocean's marine phytoplankton, vegetarian plant algae. Taking DHA supplements produced from marine algae is therefore a safe way for pregnant women to boost their fatty acid stores. And although breast feeding is the "gold standard", due to the paucity of omega-3-rich foods in the typical American diet, the amount of DHA in the breast milk of American women is far lower than that found in women in Europe and Japan.

Since its inception in 1998, Pregnant Physicians for DHA has been at the forefront of educating people about the importance of breast-feeding. They have also stressed the importance of the addition of DHA to infant formula in the United States. Notable scientific organizations such as the National Academy of Sciences, the World Health Organization (WHO) as well as the International Society for the Study of Fatty Acids and Lipids (ISSFAL) have recommended the addition of DHA to infant formula for those infants who are not breast fed. A workshop sponsored by NIH/ISSFAL recommends 300mg DHA a day for pregnant and nursing women to promote optimum neurological development and visual acuity in their babies. New research contributes to the growing body of scientific and clinical evidence that pregnant women, or women who intend to become pregnant, should consider supplementing their diets with DHA. Adding DHA derived from algae to infant formulas, in particular, is a safe and convenient way to supplement with this important fatty acid. Supplements derived from fish oil are not recommended for pregnant women and children 5 years and younger because of the potential contamination with organic toxins such as pesticides and methyl mercury. I'll talk more about that later. A study published in the July/August 2004 issue of the journal *Child Development*, found that infants whose mothers had higher blood levels of DHA at delivery had advanced levels of attention spans well into their second year of life. During the first six months of life, these infants were two months ahead of those babies whose mothers had lower DHA levels. These discoveries add to the documentation that DHA plays an important role in early development.

Omega 3 Fatty Acids and Cardiovascular Diseases

According to the American Heart Association (AHA) and the National Heart, Lung, and Blood Institute (NHLBI), the cost of cardiovascular disease and stroke in 2004 is estimated to be $368.4 billion, including both direct and indirect costs, which include lost productivity resulting from illness and death. And this is only the economic cost. The cost in human terms of suffering and lost lives is incalculable.

I would like to commend the American Heart Association (AHA) for its recent Scientific Statement on Fish Consumption, Fish Oil, Omega-3 Fatty Acids, and Cardiovascular Disease.[3]

The statement confirms the importance of two long-chain omega-3 fatty acids, docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) for their

significant role in the reduction of cardiac death. The AHA recommends that patients with coronary artery disease and hypertriglyceridemic patients consume 1g and 2-4g daily of long-chain omega-3, respectively, as part of their medical management.

The statement, however, points out a risk factor important to consider when recommending that a patient's diet be fortified with DHA and EPA from fish. Both the United States Food and Drug Administration (FDA) and the Environmental Protection Agency have recently scrutinized certain fish such as shark, swordfish, and fresh/frozen tuna for having potentially high levels of methyl mercury. In fact, the methyl mercury content of fish was cited as a potential reason for inconsistencies among studies regarding the cardiovascular health benefits of DHA and EPA from fish. For example, Salonen et al. (2000) reported that in a study of hair mercury content in 1,014 men, the highest quintile of methyl mercury was associated with a 32% greater carotid intima-media thickness compared to the lowest quintile.[4] This suggests accelerated progression of carotid atherosclerosis in response to methyl mercury exposure. In light of these findings, the AHA tempers its recommendation to increase DHA and EPA intake by stating that "the availability of high-quality omega-3 fatty acid supplements, free of contaminants, is an important prerequisite to their extensive use."

Calcium

Calcium intake is essential in youth to build peak bone mass. In later life, ongoing attention to calcium helps reduce the rate of bone loss that naturally occurs. Prolonged low calcium intake has been linked to the development of several chronic diseases, including colon cancer,[5-8] hypertension,[9-11] and osteoporosis.[5] It has been proposed that disease occurs either when the body's adaptation to low calcium intake is inadequate to maintain critical calcium regulatory system or when the constant, forced adaptive response itself produces adverse consequences.

Calcium is a critical consideration for individuals who are undergoing treatment or recovering from cancer and other major illnesses. If calcium needs are ignored during this pivotal time of treatment and recovery, an individual may conquer one terrifying disease, only to face another: osteoporosis—the devastating disease of brittle bones. Each year, osteoporosis causes more than 1.5 million bone fractures of the hip, spine, wrist or other site, draining more than $14 billion from the U.S. healthcare system. It is a painful, debilitating, and in some cases, life-threatening disease.[12]

Adequate intake of calcium is essential and it is generally accepted that the ideal method for obtaining calcium is through regular dietary sources. One reason that high calcium foods are the preferred source of calcium for maintaining calcium balance is because they contain additional essential nutrients.[13] Unfortunately, meeting the recommended daily intake of calcium has proven to be difficult for

the average American, as evidenced by the low percentage of individuals actually meeting recommended calcium intake levels on a continuing daily basis.[14,15] In the recent National Health and Nutrition Examination Survey,[16] it was reported that the average intake of calcium for women age 40 and over was only 698 mg/day. This is well below the 1500 mg/day calcium intake recommended for postmenopausal women.[14]

Meeting the calcium intake requirements can prove to be especially difficult in vegetarians and the lactose intolerant, as the primary source of dietary calcium is usually dairy products. There are an increasing number of foods being fortified with calcium, including cereals, orange juice, and some soy products, which could help to increase calcium intake in these special populations.

In those who are unable or unwilling to change their dietary habits to include enough calcium-containing foods to meet the daily recommended intake of calcium, calcium supplements are and should continue to be strongly encouraged. These dietary supplements are available in the form of various calcium salts. Not only can supplements help to increase the intake of calcium among our population but also the resultant disease prevention can help cut health care costs. There are as yet no guidelines available for the use of supplements and this is something that should be seriously considered.

Thank you for the opportunity to speak with you about these important nutrition issues.

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Mr. BURTON. You know, before we go to the next witness, I always find it very interesting that the EPA is talking about being very careful about how much fish we eat that might have mercury in it, because the environment has been contaminated with mercury, you know, and yet most of the adult shots that we get, where we get a vaccination, contain mercury. They have that in there as a preservative.

I mean, they will tell you not to eat it, but when you go to get a tetanus shot or a flu shot, they are going to stick mercury in your body. They say it doesn't hurt anything. And we have a huge increase; we have gone from 1 in 10,000 children that are autistic to 1 in 166. We have an epidemic of Alzheimer's. And we know that mercury causes neurological problems, and yet our health agencies—I know the gentleman is here from a health agency. I don't know if he is going to carry this message back, but it just seems reasonable to me that maybe we ought to get mercury out of these shots. Just get it out of there. Hell, if we can't eat it, we sure don't want to have it stuck in our bodies.

Anyhow, Mr. Balbert.

Mr. BALBERT. Chairman Burton and members of the committee, thank you for the opportunity to address you as a representative of the dietary supplement industry.

I am Elliot Balbert, CEO of Natrol, Inc. Natrol is a diversified nutrition company and manufactures and markets premium-branded nutritional products for a wide range of consumer needs.

While running Natrol is obviously an important and central role for me, I am here in another capacity, as chairman of a not-for-profit group, the Dietary Supplement Education Alliance [DSEA]. DSEA was created in 2001 as a way for my industry to help ensure that the intent of the Dietary Supplement Health and Education Act [DSHEA], is met by providing meaningful information about the health benefits and responsible use of dietary supplements to all Americans.

As you well know, Mr. Chairman, an important aspect of the passage of this critical law was to ensure that all of us as potential consumers of dietary supplements were educated about them, the very reason for the E in DSHEA. For that reason, those of us involved in DSEA have worked over the past 3 years to educate the public, the media, and even Members of Congress and their staffs through our Web site, supplementinfo.org, and other educational activities and means.

In fact, one of our ongoing educational efforts is a monthly mailing to Members of Congress, where we strive to provide those of you on the Hill with essential information on the benefits of supplements. This may be a familiar package that you have seen.

Mr. BURTON. Do those contain supplements?

Mr. BALBERT. Yes, they do. I can show you that if you would like to see those.

Mr. BURTON. No, just keep sending them.

Mr. BALBERT. Our pleasure.

Mr. BURTON. I don't want to interrupt your testimony, but something very humorous is I take so many supplements that I don't eat anymore. There is no more room for food. It is supplements and more supplements. I wish somebody would tell me what I really—

I know I need vitamin C and E and all of this, but I wish somebody would say, Danny—that is me—this is what you ought to take every day. But everybody that I know that knows that I am very concerned and want to make sure that the supplement industry does very well, because I believe very strongly in it, as you know, as the chairman of the caucus, but there has to be a limit to how much of this stuff I can take. I know I am going to live to be 170, but I would like to know if I can cut down a little bit, because I am afraid if I stop taking this, I am making a mistake and so forth.

So somebody needs to write me a letter and say, OK, this what you ought to take. Marilu, maybe it is you.

Ms. HENNER. I have it.

Mr. BURTON. I may read your book. I want you to keep me young. I am 29 now, but I want to stay there.

Ms. HENNER. You only look 27.

Mr. BURTON. I love you. I love you.

Go ahead, Mr. Balbert.

Mr. BALBERT. Well, before I continue, Mr. Chairman, we want to thank you on behalf of the industry for single-handedly supporting the ongoing efforts to help educate folks.

As a representative of DSHEA, I have three important points to make here, and I will be brief. First, as you have heard from Dr. Blumberg and Dr. Levine, dietary supplements have been shown to be safe and effective aids for maintaining health and supporting overall wellness.

Just think about the implications of this on the human level. Dietary supplements can help prevent a life of disability due to neural tube defects. Dietary supplements can enable senior citizens to live fuller lives without the disability of a broken hip. Dietary supplements can help active adults have less discomfort from arthritic knees.

The potential goes on and on. And how do you put a dollar and cents value on the quality of life? You simply cannot. This isn't a matter of statistics. It is the ability to lead healthy, happy lives.

Second, these relatively inexpensive supplements can help our country with the critical issue of managing health care costs. One of the most pressing problems confronting the United States today is the spiraling cost of medical health care. That is no mystery, and as you heard from Dr. Dobson, just two dietary supplements examined in the study could provide—I don't know if we fully grasped his statement—just two, just two dietary supplements examined in this study could provide over $15 billion in savings over the next 5 years. That is two.

We have a critical crisis going on in our health care system, and we are talking about food supplements that can help reduce health care costs, and we are not even talking about the value of the quality of life.

Third, to take advantage of health-promoting and cost-savings potential of supplements, people need accurate, science-based information about dietary supplements and access to them. To ensure that dietary supplements get the research attention they deserve, ongoing support from the Office of Dietary Supplements [ODS], Mr. Coates's office, and the National Center for Complementary and Alternative Medicine [NCCAM], is essential.

We would urge members of your committee to strive to find ways to increase funding to these government bodies. We are confident that more extensive research will only further support the benefits, safety, effectiveness, and cost savings we are hearing about in this panel today.

To promote education about supplements, full implementation of the Dietary Supplement Education Act is important. Chairman Burton, we applaud your recognition of this critical aspect; on behalf of the industry, praise your efforts to achieve this goal by your introduction of H.R. 4760, which I wholeheartedly support.

I believe there is more that can and should be done to ensure that consumers have access to balanced, science-based facts about dietary supplements so they may make informed decisions about achieving and maintaining optimum health. That is really what this is all about.

To ensure even greater access to supplements, bills like your Tax Fairness Act are critical and represent legislation we endorse. The Tax Fairness Act would allow taxpayers to deduct amounts paid for foods for specialty dietary uses, dietary supplements or medical foods as medical expenses, thereby fairly putting supplements on par with other health benefits.

Likewise, the ability of food stamp recipients to use their benefits to purchase dietary supplements. Food stamps can be used to buy Twinkies, but they can't be used to buy dietary supplements.

As you and others have proposed in the past, Mr. Chairman, this is an idea we hope you and others will pursue.

In closing, I would like to point out although many congressional hearings focus on what is wrong, hearings like this provide encouragement to continue doing what is not only right, but cost-effective, too. I want to thank the chairman and others on the subcommittee for taking the time address to the positive aspects of dietary supplements. Thank you, sir.

Mr. BURTON. Thank you.

[The prepared statement of Mr. Balbert follows:]

TESTIMONY OF ELLIOTT BALBERT
BEFORE
THE COMMITTEE ON GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES
September 22, 2004

Chairman Burton and Honorable Members of the Committee, thank you for the opportunity to address you as a representative of the dietary supplement industry. I am Elliott Balbert, CEO of Natrol, Inc. Natrol is a diversified nutrition company that manufactures and markets premium branded, nutritional products for a wide range of consumer needs. While running Natrol is obviously an important and central role for me, I am here in another capacity, as Chairman of a not-for-profit group, the Dietary Supplement Education Alliance, known as DSEA.

DSEA was created in 2001 as a way for my industry to help ensure that the intent of the Dietary Supplement Health and Education Act (DSHEA) is met by providing meaningful information about the health benefits and responsible use of dietary supplements to all Americans. As you well know Mr. Chairman, an important aspect of the passage of this critical law was to ensure that all of us as potential consumers of dietary supplements were educated about them – the very reason for the "E" in DSHEA. For that very reason, those of us involved in DSEA have worked hard over the past three years to educate the public, the media and even members of Congress and their staffs through our website, www.supplementinfo.org, and other educational activities and means. In fact, one of our ongoing educational efforts is a monthly mailing to members of Congress where we strive to provide those of you on the Hill with essential information on the benefits of supplements.

As a representative of DSEA, I have three important points to make here today.

First, as you've heard from Dr. Blumberg and Dr. Levine**, dietary supplements have been shown to be safe and effective aids for maintaining health and preventing disease**.

Just think about the implications of this on a human level: dietary supplements can help prevent a life of disability due to neural tube defects; dietary supplements can enable senior citizens to live fuller lives without the disability of a broken hip; dietary supplements can help active adults have less discomfort from arthritic knees; the potential goes on and on.

This isn't a matter of statistics; it's a matter of the ability to lead healthy, happy lives. As Ms. Henner has described, the use of supplements can make a huge difference to real people.

Second, these relatively inexpensive supplements can help our country with the critical issue of managing health care costs.

One of the most pressing problems confronting the U.S. today is the spiraling cost of medical care. As you've heard from Dr. Dobson, just two dietary supplements examined in this study could provide over $15 billion in savings in the next five years.

The study outlined today examined the cost saving ability of just a few supplements. Many more are available with tremendous potential to help improve health status and also avoid high cost medical services. Dietary supplements can be a potent tool in our efforts to manage health care costs.

Third, to take advantage of the health-promoting and cost-saving potential of supplements, people need accurate, science-based information about dietary supplements and access to them.

To ensure that dietary supplements get the research attention they deserve, ongoing support for the Office of Dietary Supplements (ODS) and National Center for Complementary and Alternative Medicine (NCCAM) is essential. We would urge members of this Subcommittee to strive to find ways to increase funding to these governmental bodies. We are confident that more extensive research will only further support the benefits, safety, effectiveness and cost savings we heard about in today's hearing.

To promote education about supplements, full implementation of the Dietary Supplement Health and Education Act is important. Chairman Burton, we applaud your recognition of this critical aspect and praise your efforts to achieve this goal by your introduction of H.R. 4747, which I wholeheartedly support. I believe there is more that can and should to be done to ensure that consumers have access to balanced, science-based facts about dietary supplements so they can make informed decisions about achieving and maintaining optimum health.

To ensure even greater access to supplements, bills like your Tax Fairness Act are critical, and represent legislation we endorse. The Tax Fairness Act would allow taxpayers to deduct amounts paid for foods for special dietary uses, dietary supplements, or medical foods as medical expenses – thereby fairly putting supplements on par with other health benefits. Likewise, the ability of food stamp recipients to use their benefits to purchase dietary supplements, as you and others have proposed in the past, Mr. Chairman, is an idea we hope will be pursued in future legislation.

In closing, I would like point out that although many congressional hearings focus on what's gone wrong, hearings like this provide encouragement to continue doing what's not only right to do, but cost effective too. I want to thank the

Chairman and others on the Subcommittee for taking the time to address the positive aspects of dietary supplements.

Mr. BURTON. And I do take a myriad of supplements, but, like I said, I think that might be one of the problems with a lot of people, because there are so many supplements that are available in the marketplace to take care of a myriad of problems that you sometimes wonder, you know, if you are—if you are taking too many, or if you are not taking enough.

So I am going to read Ms. Henner's book, I have it right here. She looks awful nice. Does this tell me how to do that?

Ms. HENNER. Sure. If not, I will give you my e-mail address, and I can send you a lot of information.

Mr. BURTON. Gosh, that would be great. I would love just to converse with you. You are a lovely lady. OK.

Ms. HENNER. Well, thank you so much.

Well, Chairman Burton, good morning, and members of the committee. I am Marilu Henner, actress, author, concerned mother, and health advocate. As a consumer who recognizes the value of dietary supplements, I thank you for the opportunity to speak here today.

I would like to provide testimony on why I believe it is important for consumers to have information about dietary supplements and to have access to supplements through their government and private health plans. The information and access is important in order to help people make better decisions and lead healthier lives than is possible through a healthy diet alone. I mean, that is why I believe dietary supplements should be part of a campaign to improve our Nation's health.

Now, I feel qualified to say that, because I am not only the author of six best-selling books promoting health and nutrition and a healthy lifestyle, but I am also one of the healthiest eaters in Hollywood; that is, according to a few magazines. Which isn't saying much, because everybody is on that crazy low-carb phase except me.

Anyway, I believe that healthy food without dietary supplements is not enough, because it is not always possible to get everything we need from our food, no matter how carefully we plan our diet. We eat in restaurants, we eat on airplanes, we eat in school lunch programs, etc.

But before I get into my personal story, I would like to talk first about the need for information. According to the Centers for Disease Control, approximately 400,000 Americans a year die as a result of an unhealthy diet and a sedentary lifestyle. While I personally think the estimate is low, it is high enough for us to recognize that something must be done to get people moving and eating better.

As the waistline of the average American continues to expand, illnesses related to obesity, such as diabetes and heart disease, are reaching epidemic proportions. People are stuffing themselves with processed foods and fast foods and junk foods, while they are literally starving their bodies of the nutrients they need.

The solution for too many people is fad diets that only perpetuate their unhealthy eating habits. As I have described in several of my books, I was raised on the standard American diet and spent many years dieting as I tried to control my weight. I actually weighed 54 pounds heavier than I do right now. Big change. The result, of

course, was that I was consistently in bad health and never could control my weight eating that way. Both of my parents died in their fifties of diseases associated with poor diet. As I have since learned, my father's heart disease could have probably been mitigated using vitamin E and omega–3 fatty acids, and the severity of my mother's arthritis could have been alleviated using calcium and/or glucosamine.

I have had my own experiences with calcium. I have not had a dairy product in 26 years. I take a calcium supplement. I had a bone density test recently. I am the 104th percentile for a woman my age. I am 52. I was in the 97th to 99th percentile for a woman 18 to 25, and this is—I had a mother who died of arthritis. So I know that a calcium supplement can definitely help, and, you know, coupled with a very healthy diet of leafy greens, etc., salmon.

My parents' deaths were the impetus for my never-ending quest for better health for myself, my siblings, my children and anyone else who would listen. My journey to good health took many years. Mine was a story of trial and error, because it was so difficult in the 1970's and 1980's to find information about optimizing health through diet and supplements. There is more information now than ever before about health, but unfortunately the same chatter about fad diets and miracle drugs drowns out the sound information that people should be getting.

I believe that people are ready to take the right steps toward becoming healthy, but without the proper guidance and the support of their insurance providers, health organizations and the Federal Government, they will continue to be led into to seeking false solutions. One of my goals as an author is to show people the way to optimize their health by encouraging them to disregard false solutions such as drastic weight loss with no sacrifice, or better health through miracle pills. I really do believe it is about changing the palate of America.

Through my many personal appearances advocating good health, my books and my Web site at marilu.com, I come into contact with and mentor thousands or people who are on their own quest for good health. I hear many personal accounts of how people have turned their lives around from debilitating illness to vibrant health when they get information needed to make choices, to make good choices, and by good choices I mean specifically rejecting the manufactured foods of our society with their overreliance on sugar, meat and dairy, and the chemical, hormones and steroids that usually accompany these products. Instead we should be moving toward an organic, plant-based diet that produces a sense of physical well-being, and also a healthy diet that includes the use of appropriate dietary supplements.

Finally, I would like to describe why I think it is important to have access to dietary supplements. Eleven years ago when I was pregnant with my first son, I began to take prenatal vitamins and supplements and found that I felt better than ever before. I continued to take dietary supplements after my pregnancy to benefit from the essential nutrients that I knew I couldn't get from food alone, even though I am very committed to a healthy way of eating. But I was lucky enough to have a doctor who not only understood the value of dietary supplements, he also encouraged me to use

them to maintain my health. Not everyone is that lucky, however, and many doctors have no idea what supplements are best for their patient's individual needs.

Since then I have taken dietary supplements every day, and I would recommend them to my family and friends as well as in my books and classes. The general public needs more access to dietary supplements to maintain good health. Supplements are the result of American research and development, but for some reason they have been stigmatized by the American Medical Association and the drug companies, and, as a result, most Americans do not have access to those supplements because they are not covered by their health plans, nor recognized as effective by the Federal Government.

I think this needs to be changed. People need to be able to find the supplements to target their specific needs. They need good information. They need to be able to find quality products, and the product needs to be cost-effective. They can't have any of these things without your help.

I have the benefits of 26 years of research and experimentation, and I have never been afraid to think outside the box when it comes to my health, but I only wish I had that information when my parents were alive, because I know I could have helped them and saved their lives.

In closing, I want to thank the committee for examining the issue and inviting me to speak here today. I would like to encourage you to make this information on dietary supplements available to all Americans so that the health of the American public can be improved. And I wish you the best of health.

[The prepared statement of Ms. Henner follows:]

TESTIMONY OF MARILU HENNER

Before

The Subcommittee on Human Rights & Wellness

of the House Government Reform Committee

U. S. HOUSE OF REPRESENTATIVES

September 22, 2004

Chairman Burton and Honorable Members of the Committee, I am Marilu Henner, actress, author and health advocate. As a consumer who recognizes the value of dietary supplements, I thank you for the opportunity to speak here today.

I would like to provide testimony on why I believe it is important for consumers to have **information about dietary supplements,** and to have **access to supplements through their government and private health plans.** The information and access is important in order to help people make better decisions and lead healthier lives than is possible through a healthy diet alone. That is why I believe that dietary supplements should be part of a campaign to improve our nation's health.

I feel qualified to say that because I am not only the author of six best-selling books promoting a healthy lifestyle, but I am also known as one of the healthiest eaters in Hollywood. I believe that healthy food without dietary supplements is not enough. It is

not always possible to get everything we need from our food; no matter how carefully we plan our diet.

Before I get into my personal story, I'd like to talk first about the need for information. According to the Center for Disease Control, approximately 400,000 Americans a year die as a result of an unhealthy diet and a sedentary lifestyle. While I personally think this estimate is low, it's high enough for us to recognize that something must be done to get people moving and eating better. As the waistline of the average American continues to expand, illnesses related to obesity, such as diabetes and heart disease are reaching epidemic proportions. People are stuffing themselves with processed foods and fast food while they are literally starving their bodies of the nutrients they need. The solution for too many people is fad diets that only perpetuate their unhealthy eating habits.

As I have described in several of my books, I was raised on the Standard American Diet, and spent many years yo-yo dieting as I tried to control my weight. The result of course, was that I was consistently in bad health and never could control my weight eating that way. Both of my parents died in their fifties of diseases associated with poor diet. As I have since learned, my father's heart disease could have probably been mitigated using Vitamin E, and the severity of my mother's arthritis could have been alleviated using Calcium and/or glucosamine. My parents' deaths were the impetus for my never-ending quest for better health for myself, my siblings, my children and anyone else who would listen.

My journey to good health took many years. Mine was a story of trial and error, because it was so difficult in the 1970's and 80's to find information about optimizing health through diet and supplements. There is more information now than ever before about health, but unfortunately the same chatter about fad diets and miracle drugs drowns out the sound information that people should be getting. I believe that people are ready to take the right steps toward becoming healthy, but without the proper guidance and the support of their insurance providers, health organizations, and the federal government, they will continue to be led into seeking false solutions. One of my goals as an author is to show people the way to optimize their health, by encouraging them to disregard false solutions such as drastic weight loss with no sacrifice, or better health through miracle pills.

Through my many personal appearances advocating good health, my books, and my Web site at Marilu.com, I come into contact with and mentor thousands of people who are on their own quest for good health. I hear many personal accounts of how people have turned their lives around, from debilitating illness to vibrant health, when they get the information needed to make good choices. By good choices, I mean specifically rejecting the manufactured foods of our society, with their over-reliance on sugar, meat and dairy and the chemicals, hormones and steroids that usually accompany these products. Instead we should be moving towards an organic, vegan diet that produces a sense of physical well-being. I also believe that a healthy diet includes the use of appropriate dietary supplements.

Finally, I'd like to describe why I think it's important to have access to dietary supplements. When I was pregnant with my first son, I began to take prenatal vitamins and supplements, and found that I felt better than ever before. I continued to take dietary supplements after my pregnancy to benefit from the essential nutrients that I knew I couldn't get from food alone, even though I'm committed to a very healthy diet. I was lucky enough to have a doctor who not only understood the value of dietary supplements, but also encouraged me to use them to maintain my health.

Since then, I have taken dietary supplements each day, and I recommend them to my family and friends, as well as in my books and classes. The general public needs more access to dietary supplements to maintain essential good health. Supplements are the result of American research and development, but for some reason, they have been stigmatized by the American Medical Association and the drug companies. As a result, most Americans do not have access to these supplements because they are not covered by their health plans, nor recognized as effective by the federal government. I think this needs to be changed.

In closing, I want to thank the committee for examining this issue and inviting me to speak today. I would like to encourage you make this information on dietary supplements available to all Americans so that the health of the American public can be improved.

I wish you all the best of health.

Mr. BURTON. You know, I am going to use a different kind of metaphor to make this next statement. That is, you know, when we were attacked on September 11, we at that point didn't have the ability to arrest and hold a suspected terrorist before the act took place. There had to be probable cause, you know, all of the things that you do. And we ended up passing what was called the Patriot Act, so that if we saw a terrorist, we could get him and hold him until we checked him out to make sure that he didn't kill 10,000 or 12,000 people.

And that brings me to the issue we are talking about here today, and that is health. My son-in-law is a doctor, and most doctors are taught to take care of people who become sick. But they don't move in advance to help them with preventive medicine, because they are not trained that way. They are not trained to say take these supplements, take these things, and you probably won't have the kind of maladies that you may be heading for.

And it seems to me in our medical schools, in addition to what we have been talking about here today, and we talked about this at other hearings, that the medical colleges and universities around the country ought to be teaching diet, supplements, nutrition and everything right along with the medical studies so that they minimize the amount of people that have to come to them in the first place. And I think we would have a much healthier Nation.

Unfortunately, that's not the case. We have the cart before the horse. You get sick, then you go to the doctor and he gives you prescription drugs, many of which help but don't solve the problem, because the problem started earlier. So I agree with what you said, and that's why we are sponsoring all of the legislation we are to try to give people the ability to get vitamins and minerals and supplements that will help them in a preventive way from getting these diseases.

Dr. Dobson, you provided us with some very significant cost savings in the findings of your studies. Would you say that the cost savings for calcium and folic acid are conservative? And would you also agree that even more savings could be achieved by people using them?

Mr. DOBSON. Yes, they are very conservative estimates, for two reasons, No. 1, we assumed that most people wouldn't take either the calcium they should or the folic acid they should. If more people took each of those supplements, our estimates would rise.

If we had public policies that encourage people, as Marilu has suggested, to get more people to take more folic acid, we would reduce more neural tubes defect than we estimated in our studies, which would increase the savings similarly with the calcium.

Second, we only took the major healthcare savings associated with both calcium and folic acid. And as you have heard from your panel, there are many other potential savings that one might have. We didn't cost those, because the research isn't quite there yet, but it may very well be in the future. So I think for those two reasons at least, our estimates are very, very conservative.

Mr. BURTON. You also stated that omega 3 fatty acids, glucosamine and saw palmetto, that there's emerging evidence that suggests there's going to be significant cost savings for those as well. What types of research would have to be conducted to help

determine if there would be economic benefits from those supplements?

Mr. DOBSON. I think that the research already in place, the clinical trials under way by FDA and others at other Federal agencies, may be powerful enough in the next couple of years to allow the cost estimates to be made. We won't know until we get the studies, of course, but it's these very carefully controlled studies that take time and money to put in place. We need more of those for our supplements.

The government is, as we heard from Dr. Coates, is well on its way to providing those types of studies. We are focusing now in those areas where there's a long trail already of evidence that's out there, and a few additional studies may be what we need to take us over the top to be able to say, yes, these are supplements that we can now have confidence that they do improve health to the point where we can calculate cost benefits.

Mr. BURTON. Let's see, Dr. Blumberg, in your testimony, you state that all women capable of becoming pregnant need to consume folic acid on a daily basis. What would you recommend is the best method of obtaining folic acid besides eating liver, mushrooms, dried greens or green leafy vegetables. Would just taking a folic acid pill be sufficient?

Mr. BLUMBERG. Well, I would point out—it's not nearly my view, but the view of the Institutes of Medicine and the CDC—that the most effective, reliable and practical way to insure that enough folic acid is consumed to reduce the risk for neural tube defects is to take a dietary supplement containing 400 micrograms of folic acid.

It's just, hands down, the most realistic way to do it. The reason that many women don't, indeed as I stated, two-thirds of American women in this group do not use supplements containing folic acid, is they are not getting the recommendations from their health care providers that this is an appropriate thing for them to do. It's really part of the preventive nutrition issue that you were raising. This advice, which is actually official government advice, is still not being picked up by health care providers by physicians, dieticians, pharmacists and others to encourage women to do this.

Mr. BURTON. Is folic acid one of the most practical ways to insure good health?

Mr. BLUMBERG. Well, folic acid, I like to think, is a very important vitamin, but it's certainly not the only one. I would point out, for example, that folic acid works in conjunction with other B vitamins, like vitamin B6 and vitamin B12 to lower homocysteine, which I mentioned is an independent risk factor for cardiovascular disease.

As Dr. Coates mentioned, there's some exciting new research that suggests that increasing our intake of folic acid may reduce the risk for age-related dementias like Alzheimer's disease. Recent research studies at Tufts University have shown that people with elevated homocysteine levels which can be lowered by folic acid supplements, have fourfold higher rates of Alzheimer's disease than people with low homocysteine levels. So I think the promise of folic acid, together with other essential vitamins and minerals,

holds tremendous promise for promoting health and reducing our risk for many chronic diseases.

Mr. BURTON. Well, I would like for all of you, as I said before—I would like for all of you, if you would, to give me a list of the essential vitamins that people should take so that they—I personally would like to know.

I have drawers of items. I can't possibly take them all. I think that's one of the shortcomings that people have when they start deciding what is best for them. Because every article that you read says this does this, this does this, and this does this. And clarity in your health, I think, providing for your health, I think is very important. So I would like some advice from you folks, and I have been taking these things for a long time.

Dr. Levine, as part of your both written and oral testimony, you stated that Americans are not getting the recommended daily intake of calcium that they need on a daily basis, just through the foods they eat, that they are eating. Can you tell us the benefits that we are getting as a society, how it could reap more benefits if individuals supplemented their diets with calcium and what kind of calcium are we talking about, are you talking about CalMax or things like that?

Ms. LEVINE. Well, they are. Well, first some people should get some calcium from their diet. Typically they get it from dairy foods, certain leafy vegetables like cal-fortified foods, such as fortified orange juice. They can get it from fortified cereals. But really most people are unwilling or unable to get the 1,200 milligrams they need, and that's for both men and women.

That's if you translate it into dairy products, that's four glasses of milk a day—and most of us are saying low fat or skim milk a day—but most of us are unwilling or unable to do that. So you can get it from calcium carbonate, calcium citrate. You really do not want to go to bone meal or dolomite that are contaminated with things like lead or arsenic.

And the coral calcium issue is one that I don't even want to go into.

Mr. BURTON. Why not? Wait a minute. I want you to go into the coral calcium issue.

Ms. LEVINE. Because they were advertising that as having a high absorption rate of 69 percent. We know that most calcium, like carbonate or citrate, according to Dr. Heeney, who is a calcium expert, shows that most calcium is absorbed like milk at about 30 percent. So they did not do the calcium studies on coral calcium.

Mr. BURTON. Well, you are not saying coral calcium is not good, it is just——

Ms. LEVINE. There is no way that it has an absorption rate of 69 percent.

Mr. BURTON. But it's not bad?

Ms. LEVINE. I don't think we have the studies. We really need good double blind placebo-controlled studies. Most of the studies that I am involved in, either at Cornell or the Rockefeller or Strand, are in our clinical research center where we typically—I should say it this way—incarcerate our patients. They stay in the hospital. We control everything that they eat and drink.

Mr. BURTON. But you haven't studied coral calcium yet?

Ms. LEVINE. We do. We just finished a study on calcium, using calcium carbonate in patients that were at high risk for colon cancer.

Mr. BURTON. Uh-huh.

Ms. LEVINE. Those data are not quite complete yet, so we will have——

Mr. BURTON. What about the coral calcium?

Ms. LEVINE. We didn't use coral calcium.

Mr. BURTON. You haven't studied it?

Ms. LEVINE. No, we haven't studied it.

Mr. BURTON. All right. Could you further explain the benefits of omega 3 fatty acids for all Americans?

Ms. LEVINE. Yes. As I mentioned with children, it starts at the very beginning. Mom gives DHA by the placenta in the third trimester of pregnancy to her baby, and then if she is nursing her baby, she will give DHA to her baby.

However, as Americans, we have the lowest levels of DHA in our breast milk. That's because we do not eat fish, and we don't eat organ meats—and you mentioned you don't like liver. Typically, we used to eat more organ meats.

It's in liver, it's in brain. Remember that brain is made up of 60 percent fatty acids and 30 percent of which is DHA or decosahexaenoic acid, and it's also very concentrated in the retina. So, babies that get DHA have better cognitive function and visual acuity. And it's also in the heart muscle. So that we really need to have it throughout all stages of life.

And now, through the Framingham study, you mentioned that too, it's been shown that patients that have low DHA levels in their serum and then on autopsy in their brain have higher, higher incidence of Alzheimer's disease or dementia. So we need it throughout our life cycle. So it's very, very important. And I mentioned, we soon will have results in a primary—prevention trial with DHA. And that, again, is in a study that we gave everything that the patients had to eat and drink in our clinical research center.

The only thing that was different is that they were either on placebo or on DHA supplementation while in the hospital for 6 months. So it was a long-term study, and we will have the results shortly.

Mr. BURTON. Well, if I have to choose from eating a supplement that contains DHA or eating brains——

Ms. LEVINE. I'm sorry.

Mr. BURTON. I said if I have to choose between eating a supplement that has DHA or eating brains, there's not going to be any question.

Ms. LEVINE. Me too.

Mr. BURTON. Mr. Balbert, were you surprised by the $15 billion in cost savings and healthcare expenditures that were derived from the results of the study conducted by the Lewin Group?

Mr. BALBERT. I was delighted with the cost savings.

Mr. BURTON. Were you surprised?

Mr. BALBERT. Not really. Just putting a number to something that we have, I think, intuitively understood in the industry, was a pleasure and a relief. The fact of the matter is that's just a quan-

tification of a specific ailment, and I happened to put a great deal of value in the quality of life of dietary supplements.

One other comment, chairman, you have expressed a number of times in your comments about the angst that you have with the volumes of dietary supplements that you take and the difficulty that you have in finding out what is right for you. The industry has a very simple guideline on that. We suggest that everybody should take one multivitamin and mineral formula as a base of any healthy nutritional program, and then based upon the additional body functions that you are looking for sufficient nutritional support from—whether it be eye health such as lutein or insulin balance, which is chromium—you would then build around your multivitamin formula.

That, along with a good healthy life-style with plenty of sleep and rest, and you will live to that 170 that you were talking about.

Ms. LEVINE. And laughter.

Mr. BALBERT. Oh, yes, and laughter.

Mr. BURTON. OK. All right.

Your organization, the Dietary Suupplements Education Alliance, in your Web site and mailings to Capitol Hill have helped to educate Members of Congress on the benefits of taking dietary supplements.

Do I then assume correctly that it is critical that the DSHEA be preserved and not amended?

Mr. BALBERT. Absolutely, Mr. Chairman. We don't believe that there needs to be any modification for DSHEA. The Federal Food and Drug Administration has all the authority that they need. What they need to do is to encourage and implement the DSHEA, all the grounds that are necessary at this time. DSHEA does not need to be modified.

Mr. BURTON. Our health agencies have the tools necessary to police that?

Mr. BALBERT. By their open admission and testimony——

Mr. BURTON. I think they have the tools today, yes. Well there are those in Congress and in health agencies that want to junk DSHEA, as you probably know. I just want to admonish those that are interested in the health care field and the supplement field, and that they stay vigilant in contacting their Congressmen and Senators, not just Representative Kucinich, myself and Hatch and others. But contacting them and telling them how important it is, we don't tinker with DSHEA.

Ms. Henner, you stated in your testimony—you just stated that eating healthy is not enough and that you believe that dietary supplements need to be a part of your and everyone else's daily regimen.

Tell us a little bit about what you take and why you think supplements are so important to you?

Ms. HENNER. I take a multivitamin called Comprehensive Formula that I actually helped develop. I take vitamin E, I take calcium. I do take coral calcium. And I do take a calcium called Bone-Up and I—because it's vegetarian.

Mr. BURTON. You are vegetarian?

Ms. HENNER. I am what is known as pesca vegetarian. Because I eat some fish, although I have been, I eat, you know, a little bit

of fish, but I mainly eat whole grains, fruits, vegetables, legumes. So I have a very strong plant-based diet. I have just a——

Mr. BURTON. You don't drink a lot of milk?

Ms. HENNER. No, I never drink milk. My children have never had milk. They are 8 and 10 years old. They are both in a gifted school. They have both skipped a grade. And they have strong bones. They are both athletes. They are incredible. My children have never had a dairy product in their life. And I haven't had one for 26 years. So——

Mr. BURTON. Why is that?

Ms. HENNER. Because the only thing dairy is supposed to do is turn a 50-pound calf into a 350-pound cow in 6 months. It's true. I always tell people if those are your aspirations, knock yourself out.

I mean, we have a 27-foot long intestinal track in a very small stomach. A baby calf has four stomachs and 9 feet of intestines, and they have nothing to do with each other. So we are not even, you know, I think that dairy is one of the worst calcium carriers ever. Now, it doesn't even, you know, resemble the milk of old. It is really just a white bovine slime, as far as I am concerned.

Mr. BURTON. Wait a minute, I will get there. White bovine slime.

Ms. HENNER. Bovine slime, it's—you know, I read people's faces, I go up and I can always tell somebody who has an overconsumption of dairy products. Because that was my problem.

I always ate a lot of dairy products, and when I gave them up, my digestion changed, my skin changed, my weight changed. Everything changed about my body.

So I am a big advocate of people looking to alternatives to dairy products. Because two-thirds of the country doesn't even eat dairy.

So, anyway, the other things that I take are I take pycnogenol, which is an antioxidant. And I also take—but I work with a nutritionist in Los Angeles, who tests me from time to time, and also note from, based on my schedule, and based on if I am traveling, etc., I need to make adjustments along the way.

So, you know, I am lucky enough to have found someone to work with who puts me on different programs from time to time. Excuse me. Does that answer your question?

Mr. BURTON. I think so. Bovine slime.

As an author of six books promoting a healthy lifestyle, what recommendations would you make to Americans so that they can make better healthy choices?

Ms. HENNER. You mean in terms of food or supplements or both?

Mr. BURTON. Both.

Ms. HENNER. Well, I think definitely think, you know, you are a real person, eat real food. They should start reading labels. That's always where I start with people. Because anything that takes a paragraph, you know, this big to describe, or says continued on the next can, you probably shouldn't be eating it.

With my children, I always say if you can't read it, don't eat it. I always start there. And so I always have people start there. I also think that you should—the American public really needs to change their palate, because it's really not about counting, it's not about measuring, counting, you know, it's not about measuring, weighing,

counting the points, grams, carbs, etc., of the same old food. That is not going to make somebody healthy or thin or fit.

And the other thing is, I think that everyone needs a good daily multivitamin to start. And as Mr. Balbert said, you start there and then you build from there.

And then depending on your genetic hand. I knew that my parents—having died of arthritis and heart attack, that I had to, I looked into those diseases thoroughly and started taking the calcium and vitamin E and, you know, Pro-EPA is the fish oil, the one that I take.

Mr. BURTON. Besides buying your book what other things can we do to educate the public?

Ms. HENNER. Well, that's an excellent start. You know what. I always say I educated myself. I started this in 1978 after my mother died, and I went to medical libraries and research departments and took human anatomy classes and went to health food stores. And there was not a lot of information.

I think what we have to do is we have to get the information out there to people, because once you know, you can't choose not to know anymore. And this is why I am, you know, an actress who goes out talking as much as I do about health. Because I think people need to be educated.

So I think what people also need to do is also get off their butts and stop stuffing their faces but starving their bodies with the same old junk over and over again. Because that's exactly what is happening. Their bodies can't even ignore the nutrients in the food, and there's no nutrients in the foods, they choose so they keep overeating and overeating and overeating.

I always look at someone who has either a weight or skin problem, and I always say that's a natural healer. Because their body is telling them that they are doing something wrong. So I really think that what people have to do is rediscover the child in themselves, get out there and exercise, find a good doctor who can work you, know enough about your body so that you can help your doctor help you and educate yourself as much as possible. And eat lots of fruits and vegetables.

Mr. BALBERT. Mr. Chairman, the DSEA has created a very comprehensive Web site called supplementinfo.org, which is extremely exhaustive in providing information to the American public and access.

Mr. BURTON. Give me that again.

Mr. BALBERT. Supplementinfo.org contains over 2 million pages of information on the use of dietary supplements. It is ad nauseam in terms of—the information is there.

Mr. BURTON. I want a one-page, one pager.

Mr. BALBERT. We will have it prepared for you, Mr. Chairman. I can assure you.

Mr. BURTON. I want you to write down something for me saying Dan, you can do this, and you are going be all right. All right?

Mr. BALBERT. Mr. Chairman, consider it done.

Ms. LEVINE. I think other responsibilities organizations, such as the Heart Association, American Diabetes Association, of course the NIH Web site, they are excellent Web sites to go to.

Mr. BURTON. Sure. Do you know how many pieces of paper. Representative Watson and I, how many documents we have to look at a day. Do you know how many pieces of documents we get each day and constituents asking us to pass to the White House and people asking us to get their kids appointed to the Air Force Academy or West Point or God only knows, Social Security, veterans problem, we really, I am not asking for sympathy. I asked for this darn job a long time ago, but we really don't have time to go into a million pages here.

Mr. BALBERT. Of course not.

Mr. BURTON. But I will say give me the KIS principle, keep it simple.

Mr. BALBERT. I will kiss you, Mr. Chairman.

Mr. BURTON. No, thank you. Maybe Marilu Henner.

I just want to say first of all, your enthusiasm, Ms. Henner is very helpful, very nice.

Ms. HENNER. Thank you, this is my true passion, I was there yesterday at the dietary guidelines open public forum talking about—you know.

Mr. BURTON. Yes. I appreciate all of you panelists, I just want to tell you, we had a hearing about a week ago, was it, on obesity in America, and 31 percent of the people of this country are overweight. No. 65, 65 percent of the people of America are overweight and 31 percent, almost 1 out of 3 people, are considered to be obese.

I just got back from Guam and Saipan not too long ago, and they have an absolute epidemic of diabetes over there. I think we had a doctor before us at our last hearing and he said if we don't change our dietary habits in this country, one out of three children will develop diabetes in their life, newly born, one out of three.

I mean, we are looking at an absolute epidemic if we don't educate the public about eating habits, junk food—and then they start saying that the average child in a year sees about 10,000 commercials—and I started watching children's commercials and my God, Little Benny's chocolate wafers, you know, and all the stuff you see is nothing but junk food, junk food, junk food. And a bit of that is all right. But somehow, we have to educate the public, that they ought to create better food products and advertise them the way that make people want to eat them so that they get healthy. Otherwise, we are going to be paying so much money in health care cost, it's not even funny.

Ms. Watson is with us, she is my ranking democrat and a very fine lady who is really concerned about health foods. Would you like to make a comment?

Ms. WATSON. I thank you, Mr. Chairman. I am going to give my opening statement, because I think it frames my interest and concern. Natural foods and supplements are very important to a healthy population. If one understands what should go into the body, then it is possible to live a healthier and more productive life. Breast milk nurtures an infant and promotes accelerated learning.

Vitamins and minerals give cells and organs the proper building block for optimal performance. There are some supplements that have been proven to be very effective, for example, pregnant women are advised to take folic acid to reduce the risk of certain

birth defects. And calcium supplements have been demonstrated to reduce the risk of osteoporosis. Certain herbs and trace elements also have medicinal values and sickness-preventing properties.

Mr. Chairman, I am encouraged with the aggressive outreach and research initiated by the natural food and supplemental industry.

But there is room to do much more. The natural foods and supplement industry can help increasing numbers of Americans to take charge of their own health. They can assist our constituents in adopting healthier lifestyles that include a good diet, exercise, supplementation and becoming more educated about all of these.

The Dietary Supplement Health and Education Act is a very important piece of legislation, and prior to its enactment, the FDA regulated dietary supplements as food. Because manufacturers claims are often promising and completely positive, Congress created guidelines to address supplement definition, safety concerns, ingredient and nutrition labels, supplement claims, good manufacturing practices and new dietary ingredients. In addition, the DSHEA created a supplement Commission and an office of dietary supplements at the National Institutes of Health. Over the past few years, there have been several media stories of supplements causing adverse effects.

Natural nutrients are nothing to be scared of, but they should be respected, treated with care and used properly. Since the enactment of DSHEA, the FDA has issued alerts on several supplements to warn consumers of possible safety problems.

In other examples, the FDA has issued alerts about a possible liver toxicity with kava-containing dietary supplements, dangerous interactions between Saint John's Wort and a number of prescription drugs and serious kidney disease and some cancers from herbal supplements containing aristolic acid.

Until recently, the FDA has only invoked its authority to declare a supplement altered. In December 2003, the FDA declared that Efedra, a dietary supplement that was marketed for weight loss and was associated with serious adverse events, including heart attack, stroke and death, presented an unreasonable risk of injury. The courts are currently reviewing this action, and courts should not decide the risks and the efficacies of a dietary supplement at all.

On the contrary, the scientific community should reach a well-founded conclusion.

And, Mr. Chairman, you mentioned that several of the island, Guam and other areas of the north Pacific and South Pacific are now seeing the rapid development of being diabetic.

Mr. BURTON. Diabetes.

Ms. WATSON. I am thinking of so many other things. And I remember going to the Far East early—earlier on, and there wasn't a dentist around, and going back decades later, now there's a dentist on every corner. Why? Because they have started consuming western DSHEA style foods. And I think that is a sad commentary on how we are promoting our bad dietary habits around the world.

And so I hope that we will have other hearings on this issue, because I do believe that of dietary supplements have an essential role to play in today's world. And I look forward to other hearings.

I'm sorry I am late. I am sitting in another committee at the same time. So thank you very much, Mr. Chairman, for this opportunity.

Mr. BURTON. You are welcome. Before we adjourn, let me say we regret Ken Venturi wasn't here with us. Ken Venturi won the U.S. Open here at congressional under very stressful conditions years ago, he is one of my heroes, I have had a chance to get to know him and meet him a little bit. So I hope somebody will convey to Mr. Venturi our sorrow that he couldn't be with us. He has a book out, and I am hoping I get a copy of it. I would like to read it, not only on supplements but golf. I am a golf nut.

We have had some other people who are very interested in health care issues and supplements. Arnold Schwarzenegger—I talked to him on the phone—we were going to have him testify at one time, shortly after he had open heart surgery, and I asked him, this might be interesting to a lot of people who are interested in the supplement field. I asked him if he thought that supplements benefited him in the course of his surgery and his recovery. He said that he recovered much more rapidly than anybody anticipated, and he was absolutely certain it was because of not only his physical conditioning, but because of the supplements that he had been taking for years that helped him heal quicker.

Of course, we have Ms. Henner here, another celebrity, we appreciate you being here. You are very beautiful and useful.

Ms. HENNER. Thank you very much.

Mr. BURTON. Just like when I saw you on TV.

Jane Seymour is a very good friend of mine. In fact I think I am going to have lunch with Jane and James Keach, her husband, tomorrow. I think you know both of them. But she is a very, very physical culturalist, if you will, and she is also big on supplements as well as her sister, who I think teaches supplements.

And of course, we had one lady here, who I am sure would be recognized as a person of great physical stature, Raquel Welch, and just thought that you might like to know that she takes supplements as well. So this isn't just limited to the plain people like me. I mean, you have a lot of beautiful people who take that stuff as well.

Ms. WATSON. Mr. Chairman, would you yield just 1 second?

Mr. BURTON. What piqued your interest there, was it Raquel Welch or——

Ms. WATSON. This morning, on CNN, they were talking about the Greek diet, and I was in Greece for the Olympics, and I noted that every time you went into a restaurant, there was a Greek salad. And I also noticed that everyone smoked there.

And I was asking, why is it that they don't develop the kinds of cancers related to smoking? Lung cancer and etc.? And they said because of olive oil. So there are some medicinal properties in olive oil that we all should be looking into.

They also talked about couscous in place of white rice, and they talked about the fresh vegetables. They have the best tomatoes in the world. So I think there are a lot of natural products that we get through the supplements, and they tend to—they say they live longer because of the olive oil. So I think we ought to try that and, you know, stop using butter, dip our bread in olive oil. Thank you, I just had to get that in.

Mr. BURTON. Put that on my list, will you?

Ms. HENNER. I am half Greek, I just want you to know. My book has exactly what they were talking about today.

Mr. BURTON. A lot of olive oil.

Ms. HENNER. A lot of olive oil. I was raised on olive oil too.

Mr. BURTON. Send me your list, kid.

Ms. HENNER. I will.

Mr. BURTON. Thank you, this has been very, very interesting. We will have more panels on this, health and wellness and supplements. And you have been very helpful today.

We will send some questions to you. If you wouldn't mind answering them and sending them back to us for our record. Thank you very much. We stand adjourned.

[Whereupon, at 11:40 a.m., the subcommittee was adjourned.]

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