



ADDENDUM TO CRN COMMENTS ON 2010 DGAC REPORT, July 15, 2010

BENEFITS OF NUTRITIONAL SUPPLEMENTS:

SUMMARY OF 2010 EDITION

Compiled by Annette Dickinson, Ph.D.,
for the Council for Responsible Nutrition

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Council for Responsible Nutrition

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Even the most conscientious consumers find it difficult to get all the nutrients they need from food alone, and a dietary supplement can help fill nutrient gaps. While much of the current research on nutrition and health focuses on the prevention of chronic disease, most people say the primary reason they use multivitamins and other nutritional supplements is to support overall wellness. (Dwyer 2005)

The Recommended Dietary Allowances (RDA) have stood as the accepted reference value for desirable nutrient intake for almost 70 years. The latest revision, published by the Food and Nutrition Board of the Institute of Medicine in several volumes over the period from 1997 to 2004, retains the RDA as the key reference, but adds three other values. (Institute of Medicine 2006) The Estimated Average Requirement (EAR) is the amount of a nutrient that would meet the actual requirement for half of the people in a given population group. The RDA is derived by adding two standard deviations to the EAR, and the RDA remains the desirable target for individual nutrient intake. In some cases, there is not sufficient information to establish an EAR and an RDA. In those cases, an Adequate Intake (AI) is established instead. The AI is based on the amount of a given nutrient estimated to be consumed by groups of "apparently healthy people who are assumed to be maintaining an adequate nutritional state." (Institute of Medicine 2006)

The RDA and the AI are intended as targets for individual intakes, and the EAR is a tool used by researchers to determine whether a population is at risk of inadequacy or deficiency.

The UL, or Tolerable Upper Intake Level intake, is the "highest average daily nutrient intake level likely to pose no risk of adverse health effects for nearly all people in a particular group." (Institute of Medicine 2006)

LOW INTAKES OF VITAMINS A, E, C, AND B-6

National survey data shows that 93% of Americans (of all ages and both sexes) get less than the EAR for vitamin E from their diets. (Moshfegh, Goldman et al. 2005) Obviously, almost nobody gets the full RDA for vitamin E.

Although vitamin C is easy to get from normal diets, about 1/3 of Americans get less than the EAR for vitamin C from their diets. (Moshfegh, Goldman et al. 2005) Almost half have vitamin C intakes that fall below the RDA.

Smokers need more vitamin C than other people, and higher recommendations are established for them -- recommendations which more than two-thirds of adult smokers fail to meet. (Moshfegh, Goldman et al. 2005) The greatest need is for smokers to quit, but in the meantime they could perhaps do themselves some good if they at least obtained adequate amounts of the vitamins they need.

There is evidence that the current RDAs for vitamin C may actually be too low, which would make the shortfalls even greater. (Levine, Conry-Cantilena et al. 1996) (Levine, Wang et al. 2001) One of the first signs of poor vitamin C status is low energy. A study of serum levels of vitamin C in the 2003-2004 National Health and Nutrition Examination Survey (NHANES) found that 7% of the population had serum levels so low that they could be considered deficient in vitamin C. Sixteen percent of adults "had vitamin C concentrations that are associated with low energy and weakness as a result of inadequate intake of vitamin C. More than 20% of adults showed marginal vitamin C status, placing them at risk of vitamin C deficiency." (Schleicher, Carroll et al. 2009)

More than half of adults fail to obtain even the EAR for vitamin A from their diets, let alone the RDA. This shortfall could easily be remedied with a multivitamin containing a modest amount of vitamin A, preferably as a mixture of retinol and beta-carotene.

A large percent of women fail to obtain enough B-6 from their diets to meet the Recommended Dietary Allowances or even Estimated Adequate Intakes. There is new evidence to suggest, however, that the recommended intakes for vitamin B-6 may be too low. (Morris, Picciano et al. 2008)

These nutrient shortfalls are reason enough for using a multivitamin. Achieving recommended intakes is a desirable objective, and dietary supplements can help meet that goal.

LOW INTAKES OF IRON AND ZINC

A large fraction of the population also fails to consume recommended amounts of various minerals, and these shortfalls can have meaningful consequences. Low intakes of iron in women of childbearing age can have a negative impact on the ability to perform physical work as well as on cognitive function, and low intakes of zinc can have a detrimental effect on immune function, especially in the elderly. (Murray-Kolb and Beard 2007) (Brownlie, Utermohlen et al. 2004) (McClung, Karl et al. 2009)

LOW INTAKES OF CALCIUM

Calcium is a nutrient that is hard to get in adequate amounts from normal diets, except for people who consume large amounts of dairy products. National survey data show that about 90% of teenage girls, over 2/3 of women ages 19-50, and over 90% of women over 50 fall short of reaching Adequate Intakes of calcium from diet alone. (Moshfegh, Goldman et al. 2009) Men do somewhat better, but still fall short. Over 40% of men 19-50 and over 75% of men over 50 fail to get Adequate Intakes of calcium. Obviously, the vast majority of girls, women, and older men could benefit from calcium supplementation. Most calcium supplements provide about 500 mg per tablet, plus some vitamin D. One tablet in the morning and one in the evening would virtually ensure adequacy of calcium intake and also provide a boost in vitamin D.

SUPPLEMENT USE IMPROVES DIETARY ADEQUACY

Researchers from the Department of Agriculture observed that "a large proportion of older adults do not consume sufficient amounts of many nutrients from foods alone" and examined whether supplement use helped fill the gaps. (Sebastian, Cleveland et al. 2007) They confirmed that supplement use permitted more than 80% of supplement users to meet Estimated

Average Requirements for 8 nutrients, but some still fell short while others exceeded the UL for some nutrients. Other studies reported similar results. (Burnett-Hartman, Fitzpatrick et al. 2009) (Bailey, Dodd et al. 2010)

RATIONALITY OF NUTRITIONAL SUPPLEMENTS

Dietary improvement is a goal to be desired, without question, but changing dietary patterns is extremely difficult. On the assumption that it is better for people to obtain recommended amounts of vitamins and minerals than to limp along with low intakes, a multivitamin with minerals which can be purchased for less than a dime a day is worthy of consideration to fill a number of known nutrient gaps. Additional calcium with vitamin D is also advisable for a large fraction of the population.

WHO RECOMMENDS NUTRITIONAL DIETARY SUPPLEMENTS?

Dr. Walter Willett and Dr. Meir Stampfer, two prominent physician-researchers at Harvard Medical School and the Harvard School of Public Health, have concluded that "a daily multivitamin that does not exceed the RDA of its component vitamins makes sense for most adults." (Willett and Stampfer 2001) They recently reiterated this advice in a joint letter with Drs. Bruce Ames and Joyce McCann, following the NIH conference on multivitamins. (Ames, McCann et al. 2007)

Drs. Kathleen M. Fairfield and Robert H. Fletcher of Harvard Medical School and the Harvard School of Public Health reviewed the benefits of vitamins in protecting against chronic disease and concluded that a multivitamin would be prudent for virtually all adults. The physicians observed that "a large proportion of the general population" has less-than-optimal intakes of a number of vitamins, exposing them to increased disease risk. (Fairfield and Fletcher 2002; Fletcher and Fairfield 2002)

Dr. David Heber of the UCLA Center for Human Nutrition recommends "four vitamin supplements to complement the so-called basic four food groups." (Heber 2001) He also suggests additional supplements that may be of interest to those who are "nutrition savvy." Dr. Heber's *basic four* supplements are: a multivitamin/multimineral supplement, 400 IU vitamin E, 500 mg vitamin C, and 1000 to 1500 mg calcium.

Scientists at the USDA Human Nutrition Research Center on Aging at Tufts University observed that about 40 percent of people over 70 consume less than 2/3 of the recommended energy intake, making it difficult to get recommended amounts of nutrients. Calcium, vitamin D, and vitamin B-12 are of particular concern in the elderly, and the researchers developed a modified Food Guide Pyramid for the elderly with a flag on top "indicating that supplements of calcium, vitamin D and vitamin B-12 are frequently appropriate to promote optimal health." (Russell, Rasmussen et al. 1999)

ADVICE FROM THE 2005 *DIETARY GUIDELINES FOR AMERICANS*

The 2005 *Dietary Guidelines for Americans* recognize that there is reason for concern about low intakes of some nutrients, including the following:

- For adults: calcium, potassium, fiber, magnesium, vitamin A (as carotenoids), vitamin C, and vitamin E.
- For children and adolescents: calcium, potassium, fiber, magnesium, and vitamin E.

Special needs are also recognized, including:

- B-12 supplements for people over the age of 50, because their absorption of B-12 from food may not be efficient.
- Synthetic folic acid from fortified foods or supplements for women of childbearing age who may become pregnant and for those in the first trimester of pregnancy.
- Vitamin D from fortified foods or supplements for older adults, for people with dark skin, and for people not exposed to sufficient sunlight.

POSITION OF THE AMERICAN DIETETIC ASSOCIATION

The American Dietetic Association (ADA) advocates meeting nutritional needs through wise selection of a wide variety of foods, but has adopted a policy statement recognizing that additional nutrients from supplements "can help some people meet their nutrition needs as

specified by science-based nutrition standards such as the Dietary Reference Intakes." (Marra and Boyar 2009)

The ADA statement acknowledges that multivitamin and mineral supplements "can be an effective way to increase nutrient intakes to meet recommended levels of multiple nutrients...In some cases such as with calcium, an additional supplement may be considered to help meet recommended intakes, particularly in at-risk groups (e.g., older adults) where supplementation has been shown to have positive outcomes." (Marra and Boyar 2009)

WHO USES DIETARY SUPPLEMENTS?

Dietary supplements are used by the majority of adults in the United States. (Bailey, Dodd et al. 2010) (Radimer, Bindewald et al. 2004) Usage is higher in women than in men and increases with age and education. Supplement users tend to adopt other healthy habits such as engaging in physical exercise, suggesting that supplement use is an integral part of an overall interest in wellness.

In some nutrition surveys, users of dietary supplements have been shown to have somewhat higher nutrient intakes from food alone, indicating that they pay more attention to their diets. However, the magnitude of the difference in dietary nutrient intake is small, and the intakes of many users as well as nonusers of dietary supplements fall short of recommended levels, for a number of vitamins and minerals. (Murphy, White et al. 2007; Sebastian, Cleveland et al. 2007) (Foote, Murphy et al. 2003)

An annual survey of consumer use of dietary supplements is conducted by the Council for Responsible Nutrition (CRN), a trade association of the dietary supplement industry. Each survey includes a national sample of about 2000 adults. The 2009 CRN Consumer Survey on Dietary Supplements found that 65% of the sample identified themselves as supplement users. This figure has remained fairly constant for several years. The percent who described themselves as supplement users was 64% in 2008, 68% in 2007, and 66% in 2006. (CRN 2009)

The prevalence of dietary supplement use has increased over time. For example, four national surveys conducted between 1972 and 2000 found that usage among older adults increased during that period from 30% to 44% to 55% to 63%. Usage among younger adults was

lower in each period but also approximately doubled, increasing from 20% to 29% to 30% to 43% in the four surveys. (Koplan, Annet et al. 1986; Block, Cox et al. 1988; NCHS 1999; Radimer, Bindewald et al. 2004)

A survey of supplement use among more than 18,000 women in Iowa found that usage increased from 66% in 1986 (when the women were in their 50s and 60s) to 85% in 2004 (when the women were in their 70s and 80s). The authors "suggest that the use of dietary supplements by older individuals could be beneficial in countering age-related declines in food and nutrient intakes and in maintaining adequate nutrition for nutrients for which absorption declines with age." (Park, Harnack et al. 2009)

HEALTH PROFESSIONALS ALSO USE DIETARY SUPPLEMENTS

Health professionals are as likely as the general population to use dietary supplements. A survey of women physicians found that 64% used vitamin or mineral supplements at least occasionally, and 47% used the supplements at least 5 days a week. (Frank, Bendich et al. 2000) Two surveys of health professionals enrolled in an online course on dietary supplements reported high levels of supplement use (over 80%), perhaps reflecting the interest that led them to enroll in the course. (Gardiner, Woods et al. 2006; Kemper, Gardiner et al. 2007)

A survey of 900 physicians and almost 300 nurses found that 51% of the physicians and 59% of the nurses were regular users of dietary supplements. (Dickinson, Boyon et al. 2009) Similarly, a survey of 900 physician specialists found that 37% of cardiologists, 50% of orthopedists, and 59% of dermatologists were regular supplement users. (Dickinson, Shao et al. 2010) When occasional and seasonal use were included, the usage figures were naturally even higher. At least occasional dietary supplement use was reported by 72% of physicians and 89% of nurses in the earlier study and by 56% of cardiologists, 73% of orthopedists, and 75% of dermatologists in the later study. Both surveys were sponsored by the Council for Responsible Nutrition. A third survey of registered dietitians, nurse practitioners, and pharmacists had similar results (data not yet published). Eighty-one percent of the dietitians said most people have gaps in their diets that can be filled with vitamins and other dietary supplements, and nine out of ten of them said they take supplements themselves and recommend them to their clients.

WHAT DO ESSENTIAL NUTRIENTS ACTUALLY DO ?

The functions of vitamins and essential minerals are well known, and each of them plays one or more key roles in maintaining the daily functions basic to health and to life itself. These functions are accomplished in every cell and every organ of the body, every minute of every day. Some of these functions may ultimately provide some protection against chronic diseases such as cancer and heart disease. However, it is their more mundane but vital roles in metabolism that cause vitamins and minerals to be defined as "essential nutrients."

Many of the B vitamins are involved in energy production. They are coenzymes that make it possible for your body to convert carbohydrates and fats and proteins into usable energy that can be used to run the system -- much like a power plant turns fuel into usable electricity that can run your household appliances. Other B vitamins are involved in synthesizing the basic building blocks of the body, including amino acids, proteins, enzymes, neurotransmitters, hormones, and DNA.

Iron is an essential component of hemoglobin, which travels in the blood and carries oxygen to all the cells and tissues of the body. The effects of iron deficiency can be observed long before any actual anemia develops, and those effects include reduced physical work capacity and impaired cognitive function. (Institute of Medicine 2006)

Calcium and vitamin D are both needed in adequate amounts in order to facilitate the absorption of calcium from food and in order to maintain essential levels of calcium for many metabolic functions. Calcium is of course a critical component of bone. Getting generous amounts of calcium and vitamin D can help build greater bone mass during the growth years, help slow bone loss during aging, and even help prevent or delay fractures. However, building bones is only one aspect of calcium's function. Calcium is also a critical component of extracellular and intracellular fluids, and the body puts a higher priority on maintaining a steady state of calcium than on retaining calcium in bones. In fact, the body treats the bones as a reservoir from which calcium can be withdrawn as needed to replenish the circulating supply. In a nutshell, this is why the bones are so vulnerable to low calcium intakes. If people don't get enough calcium for the most critical daily needs, the bones are robbed to make up the difference.

Calcium in the blood, muscle, and other tissues is essential for the contraction and dilation of blood vessels, muscle contraction, neural transmission, and glandular secretion. The muscles of the heart contract and relax and contract again every second of every day; the muscles of the arteries and veins react to the pumping of the heart and keep the blood flowing to all parts of the body; the muscles of the gastrointestinal tract actively push food through the system and process it along the way, taking in the nutrients you need and pushing out unwanted waste, every day; and the muscles of the diaphragm contract and relax, pulling life-giving oxygen into the lungs and expelling other gases, without ceasing.

The bones are firmly tied together and their muscles are firmly attached to them by connective tissue -- tendons and ligaments and joint tissue made of collagen. Collagen is a strong smooth white connective tissue that cushions the bones at intersections and joints so they move smoothly, that holds muscle bundles in place so they can effectively move the limbs, and that keeps the teeth firmly in place in the gums. Collagen is made by the body from scratch -- a manufacturing process which requires vitamin C.

When vitamin C is low, strong collagen will not be produced and maintained, "resulting in symptoms such as poor wound healing, the reopening of previously healed wounds, bone and joint aches, bone fractures, and improperly formed and loose teeth. Connective tissue is also important for blood vessel integrity. A vitamin C deficiency therefore causes weakened blood vessels and ruptured capillaries, which leads to symptoms such as tiny bleeds around the hair follicles, bleeding gums, and easy bruising." (Smolin and Grosvenor 2010)

In the course of normal metabolism, the cells and tissues are exposed to oxidation, which can be beneficial or can cause damage. The antioxidant defense system includes vitamin C, vitamin E, and some enzymes containing trace minerals such as selenium and zinc. (Institute of Medicine 2006)

Vitamin A is essential for normal vision, gene expression, reproduction, development of the fetus, growth, and immune function. One of the earliest signs of low vitamin A status is night blindness (slow adaptation to the dark). (Institute of Medicine 2006)

Zinc is the most abundant trace element in the cells, where it is integral to the functioning of more than 300 enzymes. (Smolin and Grosvenor 2010) It is essential for growth and

development. Impaired rate of growth in young children is often related to zinc insufficiency and can be corrected with a modest amount of zinc supplementation. Pregnancy outcomes and immune function can sometimes be improved with zinc supplementation. (Institute of Medicine 2006)

NUTRIENT EFFECTS ON ENZYME FUNCTION AND DNA

Many of the vitamins function as cofactors for enzymes, and many of the essential minerals are integral components of the hundreds of enzymes that are functioning in the body all the time. The rates of reaction are governed by enzyme kinetics -- the rate at which enzymes bind with their target compounds or their cofactors, accomplish their work, and then release the product. This rate can vary from one individual to another. Just as some people can jump high and some people can't, some people have very efficient metabolisms and other people don't. Since vitamins are the cofactors that help enzymes to function, it may sometimes be possible to boost enzyme function by giving additional amounts of some vitamins. Dr. Bruce Ames is a prominent biochemist who believes generous intakes of vitamins can "tune up" the metabolism and thus improve health or even delay aging.

"Americans' intake of the 40 essential micronutrients (vitamins, minerals, and other biochemicals that humans require) is commonly thought to be adequate. Classic deficiency diseases, such as scurvy, beriberi, pernicious anemia, and rickets, are rare. The evidence suggests, however, that much chronic metabolic damage occurs at levels between the level that causes acute micronutrient deficiency disease and the recommended dietary allowances (RDAs). ...A tune-up of micronutrient metabolism should give a marked increase in health at little cost." (Ames 2004)

It is known that there are genetic mutations that affect key enzymes, and many of these mutations result in a lower rate of reaction for the enzyme. (Ames, Elson-Schwab et al. 2002) Ames has proposed that, when nutrients are in short supply, they are allocated by the body to vital functions such as energy production, possibly at the expense of functions important to long-term health. (Ames 2006) (McCann and Ames 2009)

CALCIUM AND VITAMIN D FOR THE BONES

There is no question that a generous intake of calcium plus vitamin D will help build optimum bone mass during childhood and adolescence and will also slow the rate of bone loss that naturally occurs with aging. These combined effects help protect against the development of osteoporosis, a disease caused by failure to build adequate bone mass or by progressive bone loss during aging. Most people do not get enough calcium or vitamin D from diet alone, and in many individuals osteoporosis is only recognized when a fracture occurs. Substantial research has shown supplements to be effective in maintaining or increasing bone density.

While the bones have an obvious structural role, they also serve as the body's reservoir for calcium, since bone calcium can be mobilized and used to maintain the steady state necessary for muscle contraction and nerve transmission. Bone is not a static tissue, but is constantly being resorbed and reformed. The balance determines whether bone is being added or lost in any particular person at any particular time. In growing children, the rate of bone formation is greater than the rate of bone resorption. In healthy young adults, the two processes are about balanced. During aging, the rate of formation falls behind the rate of resorption, and there is generally a net loss of bone.

CALCIUM AND VITAMIN D INTAKES ARE INADEQUATE

National surveys show that calcium and vitamin D intakes are inadequate -- not just for some people, but for most people, and especially for women. (Moshfegh, Goldman et al. 2009) Shortfalls may be even worse than they seem, because many experts now believe that the Adequate Intakes established in 1997 for calcium and especially for vitamin D are too low. (Vieth 2004; Dawson-Hughes, Heaney et al. 2005; Holick 2006; Vieth, Bischoff-Ferrari et al. 2007) As a result of new evidence that has emerged, the Institute of Medicine has convened an expert panel to consider whether the official values should be revised. (Institute of Medicine 2009; Yetley, Brule et al. 2009)

The National Institutes of Health convened consensus conferences on osteoporosis in 1984, 1994, and again in 2000. All emphasized the importance of calcium intakes as well as other actions to reduce the risk of osteoporosis. (NIH 2000)

In a major report issued in 2004, the Surgeon General of the U.S. concluded: "Physical activity and calcium and vitamin D intake are now known to be major contributors to bone health for individuals of all ages. Even though bone disease often strikes late in life, the importance of beginning prevention at a very young age and continuing it throughout life is now well understood....It is never too late for prevention, as even older individuals with poor bone health can improve their bone health status through appropriate exercise and calcium and vitamin D intake." (Department of Health and Human Services 2004)

According to the nonprofit National Osteoporosis Foundation, about 10 million Americans already have osteoporosis, and another 34 million have low bone mass that puts them at risk for osteoporosis. **Every year, there are more than 2 million fractures due to osteoporosis.** (National Osteoporosis Foundation 2009)

The National Osteoporosis Foundation emphasizes that "the majority of Americans do not get adequate calcium on a daily basis....When the diet does not have enough calcium for our body's needs, calcium is taken from the bones....Calcium-fortified foods and calcium supplements are helpful for people who are unable to get enough calcium in their diets....People who get the recommended amount of calcium from foods do not need to take a calcium supplement. These individuals, however, still may need to take a vitamin D supplement." (National Osteoporosis Foundation 2009)

EXPANDED HEALTH CLAIM FOR CALCIUM AND VITAMIN D

The Food and Drug Administration is authorized by law to permit "health claims" in food labeling regarding nutrients scientifically demonstrated to reduce the risk of a disease. One of the first health claims approved by FDA in 1993 was for the role of calcium in protecting against osteoporosis. (FDA 1993) In 2008, FDA revised the calcium health claim to permit mention of the fact that vitamin D also plays a critical role in maintaining bone health and protecting against osteoporosis. (FDA 2008) The claim is permitted for foods or dietary supplements that provide at least 200 mg of calcium per serving. If vitamin D is included, the product must provide at least 80 International Units per serving. The FDA regulation permitting the claim suggests model language such as:

Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

NOT JUST A WOMEN'S ISSUE

Osteoporosis can also strike men, particularly older men. It has been estimated that "one in five men over the age of 50 will suffer an osteoporotic fracture during their lifetime, and men who sustain fractures have an increased mortality risk." (Khosla 2010) In fact, the incidence of osteoporosis-related fracture in men is similar to that of myocardial infarction and exceeds that of lung and prostate cancers combined. (Binkley 2009) Clearly it is just as critical for men to obtain adequate amounts of calcium and vitamin D as it is for women.

POTENTIAL BENEFITS BEYOND EFFECTS ON BONE

Some studies suggest that improved calcium and vitamin D intakes could have benefits beyond their effects on bone. These benefits could potentially affect conditions such as cancer and hypertension, as well as numerous other health risks. (Holick 2006; Heaney 2008)

A recent review attempted to define optimal vitamin D serum levels associated with multiple health outcomes. The authors assert that "a large majority of the U.S. population could benefit from vitamin D supplementation, which is a simple, highly affordable, and well-tolerated strategy that could reduce osteoporosis and fractures and could probably reduce falls associated with lower-extremity weakness, could improve dental health, and reduce the incidence of colorectal cancer in older adults." (Bischoff-Ferrari, Giovannucci et al. 2006)

Improved vitamin D status may also protect cardiovascular health. (Dobnig, Pilz et al. 2008; Giovannucci, Liu et al. 2008; Wang, Manson et al. 2010) Harvard Medical School and the Brigham and Women's Hospital are currently undertaking a large, long-term clinical trial funded by the National Institutes of Health on the effect of 2000 IU vitamin D supplementation (and/or 1 gram of omega-3 fatty acids from fish oil) on both cardiovascular and cancer outcomes (the Vitamin D and Omega-3 Trial, or VITAL). (Harvard Medical School 2009)

WHAT WOULD IT COST TO INCREASE CALCIUM INTAKE?

Food sources of calcium tend to be more expensive than dietary supplement sources. Of course, they also provide nutrients other than calcium, and they also provide calories. The cost of adding 1000 mg of calcium to the diet would be about a dime a day for an antacid (without vitamin D), about 30 cents a day for most calcium supplements with vitamin D, less than a dollar a day if the calcium comes from low fat milk, and over a dollar a day if the calcium comes from calcium-fortified cereal or orange juice. These prices are for national brands of each product. Purchasing store brands or buying on sale would decrease the cost. Whether to change overall dietary habits to make room for additional high-calcium foods or simply to add a calcium supplement is a matter of personal choice. Adding a supplement may be the easiest and most inexpensive option, but any of these alternatives would be an economical and sound investment in long-term health for any consumer.

FOLIC ACID PROTECTS AGAINST SOME BIRTH DEFECTS

One of the most exciting scientific developments in the past several decades is the finding that folic acid (one of the B vitamins) plays a critical role in protecting against neural tube birth defects such as spina bifida, when taken by women of childbearing age before conception and during early pregnancy. Most of the clinical evidence is from studies using multivitamins containing folic acid, rather than the use of folic acid *per se*.

In the U.S., approximately 3000 pregnancies are affected by neural tube birth defects (NTDs) each year, and worldwide these birth defects affect 300,000 or more pregnancies annually. (Berry, Li et al. 1999; CDC 2009) The scientific evidence makes it clear that supplementation with a multivitamin containing folic acid could prevent a large fraction of these defects.

OFFICIAL RECOMMENDATIONS

In 1992, the U.S. Public Health Service considered the available evidence and recommended that "all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other NTDs." (CDC 1992)

In its 1998 report on recommendations for the B vitamins, the Food and Nutrition Board of the Institute of Medicine outlined the evidence relating to folic acid and neural tube defects. (Institute of Medicine 1998) A number of scientific studies have shown that women who took a folic acid supplement of 360 to 800 mcg per day, *in addition to their usual diet* providing 200 to 300 mcg of dietary folate per day, had a reduced risk of having a baby with a neural tube defect. In addition to protecting against neural tube defects such as spina bifida, multivitamins and fortified foods containing folic acid have been shown in some studies to prevent other types of birth defects, including cleft palate and cleft lip and some cardiovascular malformations, according to the Food and Nutrition Board.

Based on this evidence, the Food and Nutrition Board issued new dietary recommendations for folic acid in 1998, recognizing the need for women of childbearing age to get *supplemental folic acid, over and above* the amounts that are naturally present in foods. (Institute of Medicine 1998)

Recommendation for Women Capable of Becoming Pregnant

The Food and Nutrition Board of the Institute of Medicine recommends “that women capable of becoming pregnant consume 400 mcg of folate daily from supplements, fortified foods, or both in addition to consuming food folate from a varied diet. At this time the evidence for a protective effect from folate supplements is much stronger than that for food folate.”

FDA HEALTH CLAIM AND MANDATORY ENRICHMENT

In 1996, FDA concluded that the evidence was strong enough to support a health claim that may be used in the labeling of foods and dietary supplements containing the B vitamin folic acid. The claim may state that “healthful diets with adequate folic acid may reduce a woman’s risk of having a child with a brain or spinal cord birth defect.” (FDA 1996)

Beginning in 1998, FDA required that folic acid be included among the nutrients added to enriched grain products such as flour, breads and pasta. (FDA 1996) CDC has documented a decline of 26% in the incidence of NTDs since mandatory enrichment -- a very important gain,

even if it does not match the impact that would be predicted if women got the full recommended amount of supplemental folic acid. (CDC 2004)

In 2009, the U.S. Preventive Services Task Force reviewed and reiterated its recommendation that "all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 mcg) of folic acid." (U.S. Preventive Services Task Force 2009)

COST OF 400 mcg PER DAY OF FOLIC ACID

Women can easily add 400 mcg of folic acid per day to their dietary intake by using a multivitamin containing folic acid or by consuming a breakfast cereal fortified with 400 mcg of folic acid per serving. The cost of the multivitamin supplement would be less than a dime a day, and the cost of the fortified breakfast cereal would be about 31 cents per serving without milk or 43 cents per serving with milk. All are excellent bargains, providing critically important protection from neural tube birth defects as well as overall protection of women's health.

SUPPORTING HEALTHY PREGNANCIES AND HEALTHY CHILDREN

Pregnancy strains the mother's physical and nutritional resources, and prenatal multivitamins with minerals are commonly recommended, to ensure that both the baby's and the mother's needs are met to the extent possible.

"Whatever the limitations of our current state of knowledge, it is apparent that pregnancy and lactation are periods during which good nutrition is exceptionally important. The infant is not protected from the inadequate diet of the mother." (Zeisel 2009)

The recommended intakes for many essential vitamins and minerals increase during pregnancy, and "health care providers generally recommend that pregnant women consume a standard prenatal multivitamin and multimineral supplement as insurance against inadequate micronutrient intake." (Picciano and McGuire 2009)

"The fetus is totally dependent in early pregnancy on maternal thyroxine for normal brain development." Thus, adequate iodine intake by the mother during pregnancy is critical for neural development in the fetus, and insufficiency can result in brain damage to the infant. The American Thyroid Association "recommends that women receive 150 microgram iodine

supplements daily during pregnancy and lactation and that all prenatal vitamin/mineral preparations contain 150 mcg of iodine." (Becker, Braverman et al. 2006)

In a study of 513 low-income pregnant women in Cleveland, iron supplementation (30 mg iron as ferrous sulfate) during pregnancy led to higher average birth weights and a lower incidence of low-birth-weight infants. The authors suggest that prenatal iron supplementation "deserves further examination as a measure to improve birth weight and potentially reduce health care costs." (Cogswell, Parvanta et al. 2003)

SUPPORTING HEALTHY AGING

There is substantial scientific evidence suggesting that generous intakes of a variety of nutrients can help protect vision, lung function, neurological function and cognitive ability, skin and muscle integrity, and immune function in the aging population.

"The percentage of older adults among the world's population continues to increase." While obesity is a problem for many, undernutrition "continues to be prevalent in approximately 25-40% of older adults worldwide." Undernutrition is "associated with poor health outcomes -- from inadequate diet quality and having micronutrient deficiencies, to loss of lean body and skeletal muscle mass,...as well as inflammatory stress, compromised immune function, impaired wound healing, increased susceptibility to infections, impaired physical performance, functional dependencies, depression, and being homebound. Moreover, undernutrition reduces overall quality of life and is associated with increased mortality risk." (Silver 2009)

An extensive survey of the dietary habits of 1740 healthy adults (living in Arizona and over the age of 50) showed that more than 60 percent had deficient dietary intakes of vitamin D, vitamin E, folate and calcium. Their intakes were not only below the *recommended* levels, but below the *average requirement*. (Foote, Giuliano et al. 2000)

Researchers working in rural Iowa surveyed nutrient intakes of more than 400 elderly residents. All subjects were 79 years of age or older (average age 85) and were living in the community, not in an institution. More than half lived alone. "Eighty percent of subjects reported inadequate intakes of four or more nutrients." Folate, vitamin D, and calcium intakes were inadequate in most of this elderly population. "Multivitamin/mineral supplementation with

additional calcium may be necessary for the old to achieve adequate nutrient intakes.”
(Marshall, Stumbo et al. 2001)

CATARACTS

In the Age-Related Eye Disease Study (AREDS) sponsored by NIH, a high-dose antioxidant formulation showed no significant effect on the progression of cataracts. However, most of the participants in the study were using a Centrum multivitamin in addition to the study treatment, and subsequent analysis showed that use of the multivitamin provided significant protection against cataracts. (Milton, Sperduto et al. 2006)

In the Blue Mountains Eye Study in Australia, the effect of antioxidant intake on the 10-year development of age-related cataracts was studied in 2464 subjects. "Increasing vitamin C consumption was associated with a significantly reduced 10-year risk of incident nuclear cataract...A similar but nonsignificant trend was observed for vitamins A and E and zinc." (Tan, Mitchell et al. 2008)

In the Nutrition and Vision Project (NVP), the development of cataracts in almost 500 women over the age of 50 was studied in relation to their usual nutrient intake over a period of 13 to 15 years prior to the visual exam. The prevalence of lens opacities was lower in women with higher intakes of vitamin C and in women who had used a vitamin C supplement for 10 years or more. (Jacques, Chylack et al. 2001)

Among residents of Beaver Dam, Wisconsin, the risk of developing a cataract over a period of five years was 60 percent lower in people who had used multivitamins or a supplement containing vitamin C or vitamin E for more than 10 years, compared to people who did not use such supplements. (Mares-Perlman, Lyle et al. 2000)

AGE-RELATED MACULAR DEGENERATION (AMD)

"Age-related macular degeneration (AMD) is a disease that affects the central vision. In the aging U.S. population, AMD is a major cause of visual impairment and blindness. The prevalence of AMD increases dramatically with age. Nearly 30% of Americans over the age of 75 have early signs of AMD and 7% have late-stage disease...This number is expected to triple with the increase in the aging population in the next 30 to 40 years." Low dietary and tissue

levels of lutein and zeaxanthin are modifiable risk factors for AMD, as is adiposity. (Johnson 2005)

The Age-Related Eye Disease Study (AREDS) is an 11-year multicenter trial involving more than 3600 people who had evidence of Age-Related Macular Degeneration when they entered the trial. Participants were assigned to one of four groups, with each group receiving antioxidant supplements, zinc supplements, both or a placebo. The antioxidant supplement included 500 mg vitamin C, 400 IU vitamin E and 15 mg beta-carotene. The zinc supplement included 80 mg zinc and 2 mg copper. The participants that received both the antioxidant and the zinc supplements were significantly protected from development of advanced AMD. (AREDS-8 2001)

"With this modest therapeutic effect of the AREDS formulation, the potential effect on public health of the disease burden of AMD is considerable. It is estimated that if the 8 million individuals in the United States who are at high risk of developing advanced AMD received the AREDS formulation, more than 300,000 of the 1 million persons expected to develop advanced AMD...would avoid it, and its associated vision loss, during the next 5 years." (Chew, Lindblad et al. 2009)

ANTIOXIDANTS AND THE LUNGS

"Vitamin C and vitamin E are powerful antioxidants found in the lung where they protect against oxidative damage." Vitamin A and the carotenoids also have anti-inflammatory and antioxidant activity and play a role. In a study of over 1600 adults in western New York state, researchers found that lung function improved as blood levels of the antioxidant vitamins increased. (Schunemann, Grant et al. 2001)

NUTRITION AND BRAIN FUNCTION

In a long-term study of more than 3000 Japanese-American men over 70 years of age living in Hawaii, researchers found that the use of vitamin C and vitamin E supplements significantly reduced the risk of dementia. In those without dementia, use of vitamin C or vitamin E supplements was associated with improved cognitive function. (Masaki, Losonczy et al. 2000)

“Although severe vitamin deficiencies and congenital defects are rare, milder subclinical vitamin deficiencies are not uncommon in the elderly. Interest is increasing in learning the extent to which these mild, reversible deficiencies contribute to some decline in cognitive function in the later years of life.” It is well established that deficiencies of the B vitamins involved in the single-carbon cycle have severe effects on brain function that can result in depression, dementia, and other disorders. Results of some studies “support the possibility that poor vitamin status is partially responsible for the cognitive decline seen in some elderly persons.” (Selhub, Bagley et al. 2000)

VITAMIN D AND FALLS

There is evidence that adequate vitamin D supplementation reduces the risk of falling, in the elderly. A meta-analysis of eight randomized controlled trials found that supplementation with 700 to 1000 IU per day of vitamin D reduced the risk of falling by about 20%. (Bischoff-Ferrari, Dawson-Hughes et al. 2009)

NUTRITION AND IMMUNE FUNCTION

Infectious disease places a heavy burden on the elderly, and it is likely that improved nutrition could enhance their disease resistance. If immune function could be improved in the elderly, the impact on the individual’s quality of life and on the nation’s health care cost could be substantial.

“In comparison with the general population, older Americans are twice as likely to visit the doctor and 3 times more likely to be hospitalized; their average hospital stays are twice as long, and they consume twice the number of prescription drugs.” Infection is one of the most common causes of sickness in the elderly, and older people are two to ten times more likely to die of infections than younger adults. A review of clinical trials on nutritional interventions supports “use of a daily multivitamin or trace-mineral supplement that includes zinc (elemental zinc, >20 mg/day) and selenium (100 mcg/day), with additional vitamin E to achieve a daily dosage of 200 mg/day.” (High 2001)

In a Boston study of 88 healthy people 65 years of age or more, vitamin E supplementation was found to improve some measures of immune function. Researchers at the

USDA Human Nutrition Research Center on Aging indicated that the best responses were observed in people given 200 mg of vitamin E per day. (Meydani, Meydani et al. 1997)

A study of vitamin E supplementation and respiratory infections in over 600 elderly individuals in nursing homes reported a lower incidence of upper respiratory infections, including the common cold, in the group that was given 200 IU of vitamin E daily. Everyone in the trial (the placebo group as well as the vitamin E group) also received a supplement providing half the RDA for numerous vitamins and minerals, throughout the trial. (Meydani, Leka et al. 2004)

In the course of the nursing home vitamin E study mentioned above, it was observed that more than 30% of the subjects had low serum zinc levels at the beginning of the study and also after a year of follow up, despite the fact that they were given a supplement providing 50% of the RDA of essential vitamins and minerals, including zinc, during the trial. Compared to people with low zinc levels, the elderly with normal zinc levels had a lower incidence of pneumonia, fewer prescriptions for antibiotics, a shorter duration of pneumonia, fewer days of antibiotic use, and a lower rate of all-cause mortality. (Meydani, Barnett et al. 2007)

A study by Prasad and coworkers also reported that zinc supplementation decreased the number of infections over a period of one year, compared to the placebo group, in subjects age 55 and over. (Prasad, Beck et al. 2007)

NUTRITIONAL SUPPLEMENTS SHOULD BE PROVIDED IN NURSING HOMES

Elderly persons residing in nursing homes may be particularly at risk of unrecognized inadequacies of vitamins and minerals because of difficulties in feeding and because they are already suffering from numerous diseases or disorders. While other nutritional problems observed in nursing homes may be difficult to remedy, micronutrient deficiencies can be avoided through inexpensive, safe supplementation. Dr. Connie Bales of the Duke University Medical Center emphasizes that “the benefits could be remarkable, with the potential for improvements in a number of vital functions, including but not limited to cognitive ability and immunocompetence.” (Bales 1995)

Dr. Bales concluded, “While only a small proportion of the elderly population actually resides in nursing homes at any point in time, it is likely that many of us will pass that way at some point in our lives . . . Perhaps by moving forward with a common sense approach [supplementation] for dealing with remediable nutritional problems in the facilities where they occur, we could be doing ourselves and/or our loved ones a nutritional favor—in advance.” (Bales 1995)

HEALTH PROMOTION AND DISEASE PREVENTION

Until the 1970’s, dietary improvement and nutritional adequacy were of interest to policy makers and consumers primarily based on traditional models of health and nutrition. Good diets based on the Four Food Groups and adequate nutrient intakes based on the Recommended Dietary Allowances were considered the best guides to health, but chronic disease prevention through dietary modification was not a common topic of discussion. This situation changed dramatically following publication of the 1977 report on *Dietary Goals for the United States*, prepared by the Senate Select Committee on Nutrition and Human Needs, positing a relationship between the affluent American diet and the incidence of numerous “killer diseases.” (Senate Select Committee on Nutrition and Human Needs 1977) This was followed by a cascade of other major reports on diet and disease, including the National Research Council’s 1982 report *Diet, Nutrition and Cancer*; the Surgeon General’s 1988 report *Nutrition and Health*; and the National Research Council’s 1989 report *Diet and Disease*. (National Research Council 1982; Department of Health and Human Services 1988; National Research Council 1989)

The reports asserted that improved dietary patterns, including increased intakes of fruits and vegetables and whole grains, could reduce the risk of chronic disease. They also featured extensive discussion of the components of these foods that were likely to be protective, including fiber and a number of antioxidant nutrients. The reports attempted to emphasize the importance of improved food patterns and to downplay the importance of increasing the intake of specific nutrients, but at the same time numerous clinical trials were undertaken specifically to evaluate the possibility that supplementation with some of the individual nutrients (especially the antioxidants) might reduce the risk of cancer and heart disease. For example, by 1986 the National Cancer Institute was supporting more than 20 clinical trials on specific nutrients and potential cancer prevention. (Greenwald, Sondik et al. 1986)

DESIGN OF CLINICAL TRIALS

While countless epidemiological trials support the hypothesis that dietary improvement can reduce the risk of chronic disease, the design of clinical trials to test that hypothesis is a challenge. Nevertheless, many clinical trials have in fact demonstrated benefits against disease for specific nutrients. Calcium to protect against osteoporosis, folic acid to help prevent some birth defects, and omega-3 fatty acids to reduce the risk of heart disease are among the success stories, where numerous clinical trials have confirmed the benefits suggested by observational studies. Beta-carotene for cancer prevention, vitamin E for lowering heart disease risk, B vitamins for protecting against cardiovascular disease, and selenium and vitamin E for prevention of prostate cancer are among the disappointments, where clinical trials so far have largely failed to confirm the benefits suggested by observational studies.

What factors in the design of clinical trials are responsible for success or failure? Does a negative trial mean the hypothesis of benefit has been disproven? Might a negative trial actually represent a failure to truly test the hypothesis suggested by epidemiology and other evidence? These are questions being intensely examined and vigorously debated within the scientific community.

Trials are done with single nutrients or a small number of nutrients: The epidemiological evidence points to food patterns that are related to a lower risk of disease, but changing food habits over the long term is very difficult. Thus, researchers attempt to identify the specific nutrients that are most strongly associated with protective food patterns and then design clinical trials to test whether giving supplements of those nutrients will protect against disease. However, critical nutrient interactions must be taken into account. (Heaney 2008) Meyskens and Szabo refer to the single-nutrient focus characteristic of clinical trials as the “four-legged stool problem.” (Meyskens and Szabo 2005) Nutrients are compared to the individual legs of a four-legged stool. Together, the four legs make a strong and functional unit, but tested individually, a single leg will not stand alone – and was never meant to stand alone.

Trials are usually done in populations not screened for markers of nutrient status or markers of disease risk: Subjects are generally recruited into clinical trials without regard to relevant markers of nutrient status, including for example their baseline blood nutrient levels,

markers of antioxidant status, markers of inflammatory response such as CRP (C-reactive protein), or homocysteine levels. (Jialal and Devaraj 2005; Traber 2007; Block, Jensen et al. 2009) Some have pointed out that this is equivalent to testing statins in people who do not have elevated cholesterol levels, or testing antihypertensive medications in people who do not have high blood pressure. (Halliwell 2000; Heinecke 2001)

Trials are often done in diseased populations: Even the leading causes of death from chronic disease occur at relatively low levels in the population. Thus, clinical trials are generally done in high-risk populations or in people who already have a disease, in order to increase the likelihood of having enough events over a period of several years to detect a difference between the treatment group and the placebo group, if there is in fact a difference. Is this a true test of the hypothesis? Testing disease prevention in people who are already sick may be like looking for lost keys where the light is better, instead of where the keys are more likely to be found. (Drake and Colditz 2009)

Trials are often done in people already receiving state-of-the-art treatment for their disease: The diseased or high-risk populations often selected for clinical trials have another characteristic that may limit the ability to observe an effect of a relatively mild intervention such as a vitamin supplement. These populations are already receiving all the medications considered to represent the standard of care for patients with their particular risk factors or diseases. Thus, in order to appear successful in a clinical trial, not only must the vitamin prevent progression of disease, it must provide benefits over and above those already being provided by the standard medical treatments the patients are receiving -- and which they will continue to receive throughout the duration of the trial.

Compliance and "Intent to Treat": All subjects assigned to the treatment group are included in the analysis of effects of the treatment, whether or not they complied with the treatment regimen. This is the accepted statistical convention of analyzing data according to "intent to treat." Analysis of compliers is considered subgroup analysis and thus statistically questionable. Yet in the epidemiological studies that gave rise to the hypothesis, it was only the actual use of the supplement that contributed to the apparent benefit.

Relevance of epidemiologic data, apart from the results of clinical trials: While the current emphasis on "evidence-based medicine" tends to designate randomized clinical trials as the gold standard and minimize the relevance of even rigorously designed observational studies, the evidence for such a rigid hierarchy of study designs has been questioned. (Concato 2004)

Where next? Many researchers remain convinced that improved dietary habits and some specific nutrient interventions are very likely to make large contributions to health promotion and disease prevention. Beneficial effects have already been demonstrated and are accepted as proven for calcium and vitamin D relating to bone health, for folic acid to protect against neural tube birth defects, and for dietary fiber and soluble fiber to reduce the risk of cancer and heart disease. There is also persuasive evidence for an antioxidant cocktail to help prevent eye disease and for omega-3 EPA and DHA to reduce the risk of heart disease. At the same time, there is a dilemma posed by the series of null clinical trials relating to vitamin E and coronary artery disease, the B vitamins and cardiovascular disease, and antioxidants and cancer -- trials apparently at odds with a large body of observational evidence supported by animal studies and a full understanding of the mechanisms by which these nutrients could be expected to have a beneficial effect.

Even after disappointing clinical trials on vitamin E and heart disease appeared, Steinberg expressed confidence in the antioxidant hypothesis, saying that the results "lead us to re-examine the question of what might be the appropriate nature of trials in humans, but they do not invalidate the large body of experimental evidence supporting the role for oxidative modification of LDL in atherogenesis." (Steinberg 2000) Researchers such as Traber, Frei and Beckman remain convinced that vitamin E is beneficial when taken before disease onset, as shown by some of the subgroup analyses in the Women's Health Study, and they also point out that 96% of American women and 93% of American men fail to consume even recommended amounts of vitamin E. (Traber, Frei et al. 2008) They believe "the negative evidence regarding vitamin E supplements from randomized clinical trials is more a reflection of inadequate study design and methods of analysis than proof of failure of vitamin E in primary prevention."

Some researchers see disappointing studies as proof that clinical trials as presently designed are inappropriate for complex nutrient/nutrient/disease interactions, and they call for some new thinking about the best way to scientifically evaluate such relationships. Some have

wondered whether the scientific community is ready to rethink “the reductionist medical approach” when it comes to evaluating complex diet/disease or nutrient/disease relationships. (Meyskens and Szabo 2005)

Robert Heaney of Creighton University has been outspoken about the need for a new approach to research on nutritional approaches to disease prevention, saying: “The field of nutrition must, I believe, apply the brakes to its mad, downhill rush to embrace a drug-based standard of proof, and instead, pause long enough to develop its own standards – standards that would involve both different designs and a differing approach to endpoints.” (Heaney 2008)

BENEFITS OF LONG-CHAIN OMEGA-3 FATTY ACIDS EPA AND DHA

An abundance of evidence strongly suggests that increased intakes of long chain omega-3 fatty acids can markedly reduce the risk of heart disease. The omega-3 fatty acids believed to be largely responsible for these effects include EPA and DHA (eicosapentaenoic acid and docosahexaenoic acid). These are polyunsaturated fatty acids (PUFA) with numerous double bonds.

A workshop sponsored by the International Life Sciences Institute of North America (ILSI) in 2008 evaluated the evidence on the benefits of increased consumption EPA and DHA and recommended a combined intake of 250 to 500 mg per day, to reduce the risk of heart disease. The workshop estimated that "cardiac mortality is reduced about 35% by modest EPA+DHA consumption (about 250-500 mg/d), an effect at least as great, for example, as that of statin therapy." (Harris, Mozaffarian et al. 2009)

Omega-3 fatty acids have been shown to impact several key risk factors related to heart disease. Dr. Alexander Leaf and coworkers at the Harvard Medical School and Massachusetts General Hospital in Boston have examined the effects of omega-3 fatty acids in preventing arrhythmia in heart cells and have suggested that omega-3s may prevent sudden cardiac death through this mechanism. (Leaf 2007)

While there is an abundance of research on the cardiovascular benefits of omega-3 fatty acids, it should also be recalled that these substances are critical to many physiological functions. Maternal levels of omega-3 fatty acids during pregnancy determine the levels present in the developing infant. The long chain omega-3 fatty acid DHA is particularly critical in supporting

infant growth and development, and DHA levels in newborns are correlated with birth weight, birth length, and head circumference. It has been suggested that women and their infants may benefit if the mother is supplemented with DHA during pregnancy. (Hornstra 2000)

BENEFITS OF INCREASED FIBER INTAKE

Diets that are naturally high in fiber are those that contain generous amounts of whole grains, fruits, and vegetables. The Food and Drug Administration (FDA) has concluded that diets low in fat and naturally high in dietary fiber are associated with a reduced risk of cancer and has permitted a "health claim" that can appear in labeling for foods that are good sources of dietary fiber. (FDA 1993)

The FDA has also concluded that diets low in fat and naturally high in soluble fiber are associated with a reduced risk of heart disease. Soluble fiber has been shown to lower LDL cholesterol ("bad cholesterol"), and this is the mechanism by which it is believed to lower heart disease. Based on these effects, FDA permits "health claims" on the labels of foods that are good sources of naturally-occurring soluble fiber. (FDA 1993)

In addition, FDA permits health claims for some specific soluble fibers that have been shown to lower LDL cholesterol, and these claims are permitted for foods and dietary supplements to which these soluble fiber ingredients have been added. These include soluble fibers from oats, barley, or psyllium. (FDA 1997)

The American Dietetic Association urges people to "consume adequate amounts of dietary fiber from a variety of plant foods." (Slavin 2008) Adequate Intakes for fiber were established by the Institute of Medicine in 2002, and these are based on the amounts of total fiber believed to protect against heart disease and also to reduce the risk of diabetes. Recommended levels of fiber intake may also help support regularity (avoid constipation), protect against diverticular disease, reduce blood glucose and lipid levels, and contribute to satiety.

An Adequate Intake of total fiber is suggested to be about 25 grams per day for women and about 38 grams per day for men. Usual fiber intakes in the U.S. are much lower than this -- about 15 grams per day.

"Based on current data, dietary fiber intake from whole foods or supplements may lower blood pressure, improve serum lipid levels, and reduce indicators of inflammation. Benefits may

occur with intakes of 12 to 33 g fiber per day from whole foods or up to 42.5 g fiber per day from supplements."

There is some evidence that higher fiber intakes from foods or supplements may also have some benefit in weight loss. They may increase satiety and slow the rate of energy and nutrient absorption, leading to lower blood glucose and lipid levels following a meal.

The ADA statement concludes: "Many of the diseases of public health significance -- obesity, cardiovascular disease, and type 2 diabetes -- as well as the less prevalent but no less significant diseases of colonic diverticulosis and constipation can be prevented or treated by increasing the amounts and varieties of fiber-containing foods." (Slavin 2008)

CONCLUSION

American diets frequently fall short in providing recommended amounts of vitamins and minerals, as well as other important nutrients including marine omega-3 fatty acids and fiber. Nutritional supplements can play an important role in filling nutrient gaps, and more than half of Americans use and value nutritional supplements as an integral component of their search for a healthier lifestyle. There is substantial evidence demonstrating the benefits of nutritional supplements for health promotion and disease prevention, and more research is ongoing.

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