ON DPG Chair Message:
I hope you are all having a wonderful and relaxing summer. I am currently working on preparations for the American Dietetic Association’s Food & Nutrition Conference & Expo (FNCE) to be held in Denver, October 17 to 20, 2009. We have two wonderful educational sessions planned.

On Sunday, October 18 ON DPG will be hosting our Priority Session entitled “Revised Guidelines for Enteral and Parenteral Nutrition for Cancer Patients” presented by me, along with Dr. David August. We have another exciting session scheduled for Tuesday, October 20 by ON DPG Hospice Special Interest Group Chair Anne Cox, MS, RD along with Dr. Ira Byock entitled “Dying Well: Palliative Care, Nutrition and Ethics.” I hope you are able to attend both of these sessions. We will be having our member reception on Sunday, October 18 from 5:30 – 8:30 p.m. at the Hyatt Regency Denver in the Centennial Ballroom GH. Please come by and introduce yourself.

I would like to take this chance to offer my congratulations to the new Certified Specialists in Oncology (CSO) who passed the board certification exam. We are growing in numbers! I want to thank all of the members for their continued support and creative suggestions to help make the Oncology Nutrition DPG the dynamic and productive group that it is. Check out the website, join the listserv, join a special interest group, read the newsletter, or write an article!

I look forward to seeing you all at FNCE in Denver!

Thank you,
Maureen Huhmann, DCN, RD, CSO
ON DPG Chair 2009-2010
Many Americans are now enjoying fresh vegetables from backyard gardens and fresh fruits and vegetables from farmer’s markets. Even supermarket chains understand consumers’ interest in whole, fresh foods, and sell more locally grown produce in the summertime.

This makes it easy to consume delicious foods that provide recommended levels of antioxidants and a wide variety of other nutrients, decreasing the need for dietary supplementation. But many cancer survivors are still interested in the possible health benefits of supplements, so the summer issue of Oncology Nutrition Connection provides two articles on this issue. The first discusses the pros and cons of dietary supplementation as related to cancer, and the second reviews the current regulatory framework for dietary supplements. The summer issue of ONC also provides a reprint of Weight Loss in Ambulatory Cancer Patients Prior to Initiation of Home Parenteral Nutrition, which was first published in the February 2009 issue of Support Line and describes outcomes research conducted in oncology patients. Additional features of this issue include details of ON DPG’s planned educational sessions at FNCE, a member spotlight, an oncology nutrition news brief, and messages from ADA. The summer issue of ONC is peer reviewed and qualifies for 0.5 CPEU for your Professional Development Portfolio (PDP).

Continue to enjoy the fresh, whole foods of summer, and to use your oncology nutrition knowledge to promote the health of cancer survivors!
Interpreting Research on Dietary Supplements and Cancer – What is the Take-Home Message?
Paige E. Miller, MS; Lucy Andrzejewski; William Chyan; Denise Clutter Snyder, MS, RD, CSO, LDN

Introduction
The purpose of this article is to review the literature on dietary supplement use across the cancer control continuum. The oncology dietitian often is presented with questions about recommendations for dietary supplement use. Supplements are widely used by cancer patients and survivors, with estimates as high as 81% of survivors reporting use of any vitamin or mineral supplement and 77% reporting use of any multivitamin (1). This article will carefully review the critical area of dietary supplement use for cancer prevention and also will highlight key issues related to dietary supplement use during cancer treatment and survivorship. It will conclude with best practice recommendations for the oncology dietitian.

Cancer Prevention
Many factors can contribute to cancer, which is defined as the uncontrolled growth and spread of abnormal cells. These factors can be external (e.g., diet, tobacco use, exposures to chemicals or radiation, and infectious organisms) and internal (e.g., inherited mutations, hormones, immune conditions, and metabolic mutations). Different factors can work together or sequentially to initiate or promote cancer, and it may take a number of years before the cancerous growth is detectable (2).

The American Cancer Society (ACS) estimates that 1,479,350 new cancer cases are expected to be diagnosed in 2009 (2). Any individual can develop cancer, but there are a number of risk factors that increase the likelihood of developing cancer. Increasing age is an important risk factor, and it is estimated that more than 75% of all cancers are diagnosed in people age 55 and older (2). By 2030, total projected cancer incidence is expected to be 2.3 million attributable to a marked increase in cancer diagnoses among older adults and minorities (3).

Recently, both the ACS (2006) and the American Institute for Cancer Research and the World Cancer Research Fund (AICR/WCRF) (2009) have recommended against using dietary supplements for cancer prevention (4,5). While there is evidence that a micronutrient-rich plant-based diet including fruits, vegetables, and whole grains may reduce the risk of cancer, there is limited and largely inconsistent evidence that particular dietary supplements as individual nutrients or in combination can reduce the risk of cancer. For example, the most recent AICR/WCRF report concludes that the evidence for calcium supplementation decreasing risk for colorectal cancer was probable; evidence linking higher calcium intakes (>1500 mg) with an increased risk for prostate cancer was also probable (5).

Dietary Supplement Use
According to data from the National Health and Examination Surveys (NHANES) 1999-2000, dietary supplement use has increased in the general U.S. population since the early 1970s (6). The overall prevalence of dietary supplement use was 23% in NHANES I (1971-75), 35% in NHANES II (1976-80), and 40% in NHANES III (1988-94). In NHANES 1999-2000, more than one-half of adults reported taking a dietary supplement in the past month, and 35% reported regular use of a multivitamin-multimineral (MVMM) product (7). As an additional marker of the extent of dietary supplement use in the U.S., an estimated $21 billion was spent on supplements in 2005 alone (8).

A number of studies have found that individuals who report using dietary supplements also report greater micronutrient intakes from food, as well as higher measures of overall diet quality, compared to those who do not report using supplements (9, 10). This raises concern that these individuals may be at an increased risk of excessive intakes of vitamin and minerals, particularly among those who use MVMM preparations accompanied by single nutrient...
preparations (6). Unlike pharmaceutical drugs and food additives, dietary supplements are poorly regulated by the Food and Drug Administration (FDA) (11). According to the 1994 Dietary Supplement Health and Education Act (DSHEA), supplements can be sold without FDA approval and without proven safety or efficacy. Claims that describe the intended role of the supplement in affecting normal structure or function in the body do not have to be authorized by the FDA, although the label must provide the disclaimer that the supplement is not intended to “diagnose, treat, cure or prevent any disease.” This limited federal regulation has likely contributed to both the number of available supplements on the market and the increasing use among many segments of the population, including cancer patients and survivors.

### Antioxidants and Potential Health Risks

A number of observational studies have shown inverse relationships between greater dietary intakes of single micronutrients or combinations of micronutrients and cancer risk (12–15). Antioxidants are substances that may protect cells against the effects of free radicals that can damage DNA and cell membranes. Free radicals are produced when the body breaks down food, or by environmental exposures such as tobacco smoke and radiation. Free radical induced cellular damage is a common pathway for the development (occurrence and recurrence) of cancer. The principle micronutrient antioxidants include beta-carotene and other carotenoids, vitamin C, and vitamin E, all of which can neutralize free radicals. The trace mineral selenium is also important because it aids in the proper functioning of the antioxidant enzyme systems in the body. Because the body cannot produce these essential micronutrients, antioxidants must be supplied by the diet. A myriad of plant foods are rich sources of antioxidants, including a host of different fruits, vegetables, nuts, seeds, legumes, oils, and spices.

Although antioxidants are likely cancer preventive agents when consumed in the diet, mounting evidence from several large-scale, well-known randomized controlled trials (RCTs) suggests that antioxidant supplementation may actually increase the risk for incident as well as recurrent cancer at a number of different sites (16–22). A summary of results from these RCTs can be found in Table 1. The seminal Alpha-Tocopherol Beta-Carotene Lung Cancer Prevention Trial (ATBC) was the first large-scale RCT to show an increased risk of cancer with nutrient supplementation. Researchers reported an increased risk for lung cancer and overall mortality among the high-risk population—male smokers and asbestos workers—taking beta-carotene (20 mg per day) for 5 to 8 years (16). Further follow-up from this trial indicated that the increased cancer risk remained for four years without supplementation (23).

A subsequent study, the Carotene and Retinol Efficacy Lung Cancer Chemoprevention Trial (CARET), found that daily supplementation with beta-carotene (30 mg) and preformed vitamin A (retinyl palmitate) (25,000 IU) resulted in an increased risk for lung cancer and overall mortality among current and past smokers (17). In response to the harmful effect attributable to the intervention, the active intervention was halted prior to the planned completion date (24). Although ATBC and CARET both resulted in negative cancer outcomes for beta-carotene supplementation, participants in the ATBC

### Table 1: Randomized Controlled Trials of Antioxidant Supplements and Cancer Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>No.</th>
<th>Subject characteristics</th>
<th>Duration</th>
<th>Antioxidant (daily)</th>
<th>Dose</th>
<th>Study outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATBC, 1994 (16)</td>
<td>29,133</td>
<td>Male smokers in Finland</td>
<td>6.1y</td>
<td>Vitamin E</td>
<td>50 mg</td>
<td>Decreased risk of prostate cancer*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>β-carotene</td>
<td>20 mg</td>
<td>Increased risk of lung cancer*</td>
</tr>
<tr>
<td>CARET, 1996 (17)</td>
<td>18,314</td>
<td>Past and current smokers, asbestos workers in the U.S.</td>
<td>5.5y</td>
<td>β-carotene</td>
<td>30 mg</td>
<td>Increased risk of lung cancer*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Retinol</td>
<td>2500 IU</td>
<td></td>
</tr>
<tr>
<td>SELECT, 2009 (19)</td>
<td>35,533</td>
<td>Men residing in the U.S. (inc. Puerto Rico) and Canada</td>
<td>4 y</td>
<td>Vitamin E</td>
<td>400 IU</td>
<td>Increased risk of prostate cancer (vitamin E alone)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Selenium</td>
<td>200 mcg</td>
<td>No effect on prostate cancer risk</td>
</tr>
<tr>
<td>Physicians Health Study II, 2009 (20)</td>
<td>14,641</td>
<td>U.S. male health professionals</td>
<td>10 y</td>
<td>Vitamin C</td>
<td>500 mg</td>
<td>No effect on prostate cancer or total cancer risk</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Vitamin E (every other day)</td>
<td>400 IU</td>
<td></td>
</tr>
<tr>
<td>WACS, 2009 (21)</td>
<td>7,627</td>
<td>Women</td>
<td>9.4y</td>
<td>Vitamin C</td>
<td>500 mg</td>
<td>No effect on total cancer incidence or mortality (either single supplements or combinations)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Vitamin E (every other day)</td>
<td>600 IU</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>β-carotene</td>
<td>50 mg</td>
<td></td>
</tr>
</tbody>
</table>

*Results are statistically significant (P < 0.05)
trial who were supplemented with vitamin E as alpha-tocopherol were found to have a decreased risk of developing prostate cancer (22). This led to a separate RCT entitled the Selenium and Vitamin E Cancer Prevention Trial (SELECT) (19). In SELECT, however, researchers found no protective effect of selenium but reported a modest increased risk of prostate cancer with vitamin E supplementation. Findings from an additional RCT among male health professionals indicated that neither long-term vitamin E (400 IU of alpha-tocopherol every other day) nor vitamin C (500 mg daily) supplementation reduced the risk of prostate or total cancer among male health professionals followed for 10 years (20). Among female participants at risk for heart disease in the Women's Antioxidant Cardiovascular Study (WACS)—a double-blind, placebo-controlled RCT—researchers found no overall benefit in the primary prevention of total cancer incidence or cancer mortality from the supplementation of 500 mg vitamin C daily and 600 IU vitamin E (alpha-tocopherol) and 50 mg beta-carotene every other day (21).

**Folic Acid and Potential Health Risks**

Findings from a recent RCT suggest a potential role of folic acid in enhancing the progression of early colorectal adenoma lesions to tumors (25). In contrast, a review of the epidemiological data found an inverse association of dietary folate and colorectal adenoma, which generally precede colorectal tumors (26). This apparent paradox could be related to the dual roles folate may have—one as a chemopreventive agent for healthy colorectal mucosa and the other as a cancer promoting agent when early lesions are present. It also may be related to the different forms of this B-vitamin. Dietary folate from natural sources has been associated with a decreased risk of cancer at a number of sites (26–28), whereas the synthetic form (folic acid) found in fortified food items and dietary supplements has recently come under increased investigation for its potential colorectal cancer promoting effects (25,29). In addition, newly released findings from the Aspirin/Folate Polyp Prevention Study, a RCT designed to investigate the chemopreventive effects of folic acid and aspirin against colorectal adenoma development, suggest a potential role of synthetic folic acid in prostate carcinogenesis as well (30). Folic acid, vitamin B6, and vitamin B12 supplementation were tested for their combined effect on risk for breast cancer as well as total invasive cancer in the recent Women's Antioxidant and Folic Acid Cardiovascular Study (WAFACS). The recently published study results reported that the combined B-vitamin supplementation had no effect on reducing overall risk of total invasive cancer or breast cancer among women at high risk for heart disease (31).

**Calcium and Vitamin D**

Both vitamin D and calcium have been intensively studied and investigated for their potentially anticarcinogenic effects, namely in the breast, colon, and prostate (32–40), relating to their role in regulating differentiation, proliferation, and apoptosis in normal and malignant cells. Overall, results have been inconsistent. While findings from the large Women's Health Initiative RCT did not show a significant cancer protective effect of supplemental vitamin D (400 IU per day) or calcium (1000 mg per day) over seven years (35), two recent studies pooled results from individual epidemiological studies and found significant protective effects of higher serum vitamin D \([25(OH)D]\) level against the development of colorectal cancer (41) and breast cancer (42). In a separate pooled analysis, researchers found that supplemental calcium significantly decreased colorectal cancer risk (43), a finding that is consistent with the conclusion presented in the AICR/WCRF comprehensive report that the evidence for calcium supplementation decreasing risk for colorectal cancer was probable (5). The same report concluded that the evidence linking higher total calcium intakes (>1500 mg) with an increased risk for prostate cancer was also probable. Given the inconsistency in results and the discrepancies between cancer sites, more research is needed to address the current gaps in knowledge, including whether calcium and/or vitamin D are appropriate for chemoprevention, and if so, what the most effective doses are.

**Additional Considerations: Using Dietary Supplements During Cancer Treatment**

Radiation and chemotherapy agents cause cell death by initiating free radical damage to DNA and proteins (45). To answer the key question of whether the concomitant use of supplemental antioxidants during radiation and chemotherapy is safe and efficacious, numerous systematic reviews of relevant RCTs have been conducted in recent years (44–48). Nevertheless, the most recent review by Lawenda and colleagues (46) concluded that the question remained largely unanswered despite the comprehensive nature of the investigation into the wide array of published RCTs. A common theme throughout the multiple published reviews is that critical concerns remain about the potential for harm, and these concerns may outweigh the putative reduction in treatment side effects. The underlying mechanism by which the concurrent administration of antioxidants during radiation and chemotherapy could be counterproductive or potentially harmful relates to the ability of antioxidants to exert their effects indiscriminately. In other words, tumor cells along with normal cells might be protected from the oxidative damage generated by the chemotherapeutic agents and the radiation therapy. Caution is warranted prior to recommending the use of antioxidants during treatment and additional research is sorely needed.

For instance, folic acid has been well documented to interfere with capecitabine (Xeloda) (49) and methotrexate (Folex) (50). St. John's Wort has been shown to increase the metabolism of several chemotherapy agents thereby decreasing their effectiveness (50). These agents include irinotecan (Camptosar), erlotinib (Tarceva), imatinib mesylate (Gleevec), Paclitaxel (Taxol), tamoxifen (Nolvadex), vincristine (Oncolvin), and vinblastine (Velban) (50, 51).

Despite possible adverse effects of supplement use among cancer patients, supplements may be beneficial in particular situations. Patients unable to eat a healthful diet may benefit from the use of specific supplements to maintain function and quality of life.
diet or those suffering from malabsorption or maldigestion may require supplementation (52). Furthermore, in an observational study of 1,129 non-small-cell lung patients from the Mayo Clinic lung cancer cohort, a 35% improvement in survival was associated with patients who reported using vitamins and minerals compared to nonusers of supplements (53). Although favorable, caution is warranted when interpreting the results of this study due to its reliance on self-reported supplement use, no assessment of dosage, and its observational design, which limits its ability to draw a direct cause and effect relationship on survival and quality of life. Additionally, although several confounders were considered, vitamin and mineral supplement use tends to accompany a healthy lifestyle (9,10), and a healthy lifestyle rather the vitamin and mineral supplement use may have contributed to the improved survival and quality of life observed in the study population.

**Dietary Supplement Use During Cancer Survivorship**

Cancer survivors have been found more likely to use dietary supplements compared to the general population (54,55). This is a serious concern because cancer survivors are at an increased risk for progressive, recurrent, and secondary cancer, and the possible cancer promoting effects of micronutrient supplements above United States (U.S.) recommended levels (i.e., folic acid, calcium, vitamin E, and beta-carotene) may further exacerbate this already elevated risk.

There is growing interest in vitamin D and cancer survivorship. Not only is the role of vitamin D in key carcinogenic processes becoming better understood (39), but similar to findings in the general population, high prevalence rates of vitamin D insufficiency have been measured among cancer survivors (56). Nevertheless, data on the effects of long-term, vitamin D supplementation above the current U.S. recommendation levels are lacking, and RCTs are warranted to determine whether supplementation is an appropriate course of action for cancer survivors who want to protect against recurrence and secondary cancer. Many additional questions related to vitamin D and cancer survivorship remain unanswered, including what supplement dose, if any, is appropriate, and what are the potential adverse risks associated with long-term supplementation. Some of these questions may be addressed by the current Institute of Medicine Committee to Review Dietary Reference Intakes for Vitamin D and Calcium (57), but gaps in our current knowledge should be addressed prior to recommending that cancer survivors take supplemental vitamin D for the prevention of recurrence or secondary cancer. Until more is known, recommended dosages for vitamin D supplementation for cancer survivors should be based on current age- and gender-specific levels found in the Dietary Reference Intakes (DRIs). If possible, evaluating blood levels of 25(OH)D (beneficial range is from 90 to 100 nmol/L, or 36 to 40 ng/mL) will help inform the RD concerning whether to recommend vitamin D supplementation (58).

**Conclusions and Implications for Diietetic Practice**

In light of the potential risks as well as the lack of conclusive evidence for cancer chemoprevention of dietary supplementation, one of the eight main recommendations in the most recent AICR/WCRF report is for individuals to meet nutritional needs without the use of dietary supplements, with a few exceptions, including the presence of certain illnesses or dietary inadequacy (5,32). The report further clarifies these exceptions with several examples including vitamin B12 supplementation for individuals age 50 or older who have difficulty absorbing naturally occurring B12, folic acid supplementation for women of child-bearing age, and vitamin D supplementation for those who are not exposed to a judicious amount of sunlight or individuals (such as the elderly and/or dark skinned individuals) who do not synthesize an adequate amount of vitamin D from sunlight (5).

Research to date is limited in providing clarity into the proper use and dose of vitamin and mineral supplements in relation to prognosis. The inconsistent and inconclusive findings from a wide range of studies, including observational and experimental investigations, have prevented the development of standard clinical guidelines. Future supplement trials are needed to determine effects on treatment efficacy, cancer outcomes (recurrence and survival), dosage, safety, and quality of life. Importantly, additional research into the effects of dietary supplements on cancer outcomes should include understudied minority patients and survivor groups.

RDs remain as expert resources not only for cancer patients and survivors, but also for their healthcare team on issues relating to vitamin and mineral supplement use before, during, and after a cancer diagnosis. RDs can facilitate communication among the disciplinary team, suggesting that physicians begin conversations with patients about current supplement use and reasons for either taking or considering taking a supplement. It is important to note that patients may be less forthcoming about supplement use depending on concerns about disapproval (59). One reason may be that supplement users often receive information pertaining to dietary supplements from media sources (e.g., magazines, newspapers, books, and television) and friends or relatives, rather than from RDs or other healthcare professionals (60). In

### Table 2: Considerations for Evaluating Studies before Translating Findings into Practice (61)

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the study design of high-quality?</td>
</tr>
<tr>
<td>Were life-threatening adverse effects reported?</td>
</tr>
<tr>
<td>Were the study participants different from your patients in terms of age, gender, ethnicity, health, disease-state, or some other characteristic?</td>
</tr>
<tr>
<td>Is there evidence to support safety?</td>
</tr>
<tr>
<td>Was the sample size &gt; 50 in an RCT?</td>
</tr>
<tr>
<td>Were the findings in stark contrast to the majority of other published study results?</td>
</tr>
</tbody>
</table>
addition, it is important not only to remain up-to-date on recent research findings, especially those from large-scale RCTs investigating the effects of dietary supplementation on various cancer outcomes, but also to critically evaluate the research and determine whether the results are transferable to your patients. Table 2 provides an overview of six questions that can assist the RD in evaluating the existing evidence in order to appropriately translate findings into practice.

The RD has extensive training in food and medical nutrition therapy as it relates to health and disease. In order to provide an evidence-based recommendation, the RD should assess: 1) usual food intake (using dietary assessment methods such as reviewing recalls or food records); 2) intake of fortified and functional foods; 3) ability to consume, digest, and/or absorb foods; and 4) potential nutrition impact from medical

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**Table 3: The Roles and Food Sources of Select Nutrients (62)**

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Description</th>
<th>Examples of food sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fiber (soluble)</td>
<td>Indigestible components in plant foods</td>
<td>Oat bran, beans, peas, rice bran, barley, citrus, strawberries, pears, whole grains</td>
</tr>
<tr>
<td>Folate (folic acid)</td>
<td>Water-soluble B vitamin</td>
<td>Folate: Leafy green vegetables (like spinach and turnip greens), fruits (like citrus fruits and juices), and dried beans and peas; folic acid: fortified grain products (such as enriched breads and ready-to-eat cereals)</td>
</tr>
<tr>
<td>Lutein</td>
<td>Plant carotenoid, Antioxidant</td>
<td>Carrots, squash and other orange and yellow fruits and vegetables, dark green leafy vegetables, such as spinach</td>
</tr>
<tr>
<td>Lycopene</td>
<td>Plant carotenoid, Antioxidant</td>
<td>Tomatoes, and tomato products such as marinara sauce, watermelon, pink grapefruit, apricot, guava</td>
</tr>
<tr>
<td>Magnesium</td>
<td>Mineral</td>
<td>Pumpkin seeds, almonds, soynuts, cashews, tofu, peanuts, beans, oatmeal, spinach, dairy foods</td>
</tr>
<tr>
<td>Niacin</td>
<td>Water-soluble B vitamin</td>
<td>Peanuts, chicken, tuna, salmon, almonds, potato, mushrooms, barley, lentils</td>
</tr>
<tr>
<td>Potassium</td>
<td>Mineral, Electrolyte</td>
<td>Fruits–bananas, oranges, avocado, apricots, etc; vegetables–potatoes, sweet potatoes, spinach, carrots, greens, tomatoes etc; dairy, fish, poultry</td>
</tr>
<tr>
<td>Selenium</td>
<td>Mineral, Antioxidant</td>
<td>Brazil nuts, tuna, beef, cod, turkey, enriched pasta, egg, brown rice</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>Water-soluble Vitamin, Antioxidant</td>
<td>Papaya, citrus fruits, broccoli, Brussels sprouts, peppers, strawberries, tomatoes, cauliflower, kale</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>Fat-Soluble Vitamin</td>
<td>Fish (e.g., salmon, mackerel, tuna, sardines), fortified dairy and dairy alternatives, eggs, fortified ready-to-eat cereals, shiitake mushrooms (contain a precursor form)</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>Fat-soluble Vitamin, Antioxidant</td>
<td>Wheat germ, almonds, sunflower seeds, hazelnuts, peanuts, broccoli, spinach, kiwi, mango</td>
</tr>
</tbody>
</table>

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Recommended websites for additional information about dietary supplements

- **Caring4Cancer**
  - http://www.caring4cancer.com/
- **Federal Trade Commission**
  - http://www.ftc.gov/curious
- **Memorial Sloan-Kettering Cancer Center**
- **National Cancer Institute Office of Cancer Complementary and Alternative Medicine**
  - http://www.cancer.gov/cam
- **National Center for Complementary and Alternative Medicine**
  - http://nccam.nih.gov/
- **National Institutes of Health Office of Dietary Supplements**
- **Natural Standard, The Authority on Integrative Medicine**
  - http://www.naturalstandard.com

(Continued on next page)
condition and its treatment sequelae. Although RDs do not diagnose medical conditions, there is standardized language for nutrient intake as part of the Nutrition Care Process, which includes terminology for inadequate and excess intakes of nutrients. Recommendations for specific vitamin and/or mineral supplement needs, based on supplement content rather than brand name, encompass part of the Nutrition Care Process.

The RD is instrumental in educating cancer patients, families, and survivors that vitamin and mineral supplements are not designed nor intended to be substitutes for food. Whole foods such as fruits and vegetables are often rich in components aside from vitamins and minerals, including phytochemicals, dietary fiber, and likely other healthful components yet to be identified. Although research has identified potential nutrients of interest as being associated with chemoprevention, most of these studies stem from observational studies showing that individuals or populations with greater dietary intakes of a particular nutrient have lower incidence rates of cancer. However, once the nutrient is isolated and packaged as a supplement, often in a much higher dose than can be consumed or absorbed through diet, the vitamin or mineral may act very differently, or even counter-intuitively, in the body. RDs should actively encourage patients to disclose dietary supplement use, as well as rely on their ability to educate and communicate effectively about the value of a healthful diet and the key principle of “food first.” It should be emphasized that food as a source of nutrients is the first line of defense for disease prevention or progression. The information provided in Table 3 can help RDs provide this information to their patients, steering them away from potentially harmful supplementation practices. Table 3 is designed to be a user-friendly handout listing the role and food sources of select nutrients.

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The authors would like to thank Wendy Demark-Wahnefried, PhD, RD, as principal investigator of funding support for our work in cancer survivorship. Funding support for this work was provided by National Institutes of Health CA106919 and P30AG028716

References


Dietary Supplement Health and Education Act (DSHEA): A Primer for Oncology Dietitians
Maureen Leser, MS, RD, LD, CNSD

Introduction
Cancer survivors are likely to ask their oncology dietitian whether ginger is an appropriate addition to their antiemetic therapy; if soy products will help prevent recurrence of breast cancer; or whether they should add high-dose antioxidants to their health regimen. The practice of integrating dietary supplements with conventional cancer treatments challenges registered dietitians (RDs) to keep abreast of this field. Oncology dietitians need to remain current with scientific evidence related to dietary supplements so they can steer clients away from potentially harmful products and determine whether any dietary supplements may provide health benefits. They also need to understand how dietary supplements are regulated. After reading this article (RDs) should have a better understanding of the Dietary Supplement Health and Education Act (DSHEA), which provides the regulatory framework for dietary supplements.

Background
Herbal medicines date to ancient times. The Sumerians documented the medicinal use of poppy, thyme, and mustard plant almost 6,000 years ago (1–3). Between 2,000 and 500 B.C. the Egyptians and Chinese regularly used onion, garlic, licorice, ginger, and thyme for a variety of ailments (1–3). In the 16th century herbalists and botanicals were so important to medicine that botanical gardens were frequently planted adjacent to medical schools (4). Colonial Americans, when seeking remedies for any number of physical problems, would visit their local apothecary, where pharmacists would prepare prescriptions from herbs stored in glass bottles (4). Many herbal remedies were considered effective, and approximately 30% of conventional drugs used today originated from plants. For example, digoxin originated from foxglove and morphine originated from the opium poppy (5).

Plant composition varies according to season and growing conditions, resulting in inconsistent levels of active ingredients. Pharmaceutical manufacturers developed techniques to prepare medications with specific doses and standardized quality and purity. In the 17th century, pharmacies began dispensing medications ordered from these manufacturers, and “home-made” herbal remedies fell out of favor. Today, however, many consumers are interested in “natural” remedies, and millions of Americans, including many cancer survivors, use botanicals as well as vitamins, minerals, and other dietary supplements to promote a variety of biological effects. However, there are questions about whether current legislation unfairly favors the dietary supplement industry and adequately protects consumers.

Timeline of Major Food, Drug, and Dietary Supplement Legislation

1906: Pure Food and Drug Act (6)
Passed in response to public outrage about abuses in the meatpacking industry and the sale of fraudulent and contaminated medicine, this act prohibited marketing of adulterated and misbranded food and drugs.

1938: Federal Food, Drug, and Cosmetics Act (FD&C ACT) (7)
Reacting to the death of 100 people in the United States (U.S.) who had consumed an elixir containing a diethylene glycol solvent, Congress passed the FD&C act, which required manufacturers to prove that a drug was safe before it could be marketed.

1962: Kefauver-Harris Amendment (8–9)
Following the [European] epidemic of birth defects related to thalidomide, this amendment required that drug companies submit to FDA information that established the effectiveness and safety of their drugs prior to approval. Furthermore, the Kefauver-Harris Amendment required that drugs on the market prior to 1962 be classified as effective, ineffective, or needing further study. To assist the FDA in this endeavor, the National Research Council conducted a Drug Efficacy Study (8–9). Over-the-counter drugs, which at the time included herbal products, were also reviewed. Relatively few herbal products were placed in category I, indicating they were safe and effective. Most herbal products were categorized as not being effective or safe (category II) or lacking sufficient evidence to determine safety and/or efficacy (category III). Basing these decisions on existing evidence rather than new trials (which were cost prohibitive) meant that some products classified as ‘ineffective’ may have been used safely and/or effectively for centuries, but lacked research data to be classified in category I.

1976: Vitamin-Mineral Amendment to the Federal Food, Drug, and Cosmetic Act (10)
Also known as the Proxmire amendment, the legislation prohibited the FDA from establishing standards to limit the potency of vitamins and minerals in food supplements or regulating them as drugs based solely on their potency.

1990: Nutrition Labeling and Education Act (NLEA) (11)
The primary intent of the Nutrition Labeling and Education Act (NLEA) of 1990 was to educate consumers about the nutrient content of most foods and establish
standards for food descriptors such as “low fat” (a nutrient content claim) and health claims (11). Health claims must adhere to specific regulatory requirements and are only allowed when supported by evidence from well-designed studies indicating significant scientific agreement, and by experts qualified by scientific training and experiences to evaluate such claims (3,11).


1994: Dietary Supplement Health and Education Act (DSHEA) (13)

DSHEA established the current regulatory framework for dietary supplements, and expanded the variety of substances that could be dietary ingredients in a dietary supplement. The legislation placed dietary supplements in a special category under the general umbrella of “foods,” not drugs.

The Impact of DSHEA

DSHEA changed both the definition and regulation of dietary supplements, and triggered growth of what has become a multibillion dollar industry. Between 1990 and 1997, the prevalence of high-dose vitamin and herbal use increased by 130 and 380%, respectively (14). The National Health and Nutrition Examination Survey (NHANES) of 1999-2000 suggests that over 50% of Americans take some form of dietary supplement (15). Reports also suggest that people with medical conditions are more likely to use dietary supplements than are healthy individuals (16–17). After passage of DSHEA sales of dietary supplements in the United States increased to $17.1 billion in 2000 (3); that figure rose to $22 billion dollars in 2007 (18).

**Dietary supplements have been defined by DSHEA as a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the above (12).**

The phrase “reasonably expected to be safe”, which applies to a dietary supplement containing a new ingredient, (19,21) has received criticism for allowing manufacturers to demonstrate safety with research sponsored by pharmaceutical companies or that does not meet rigorous research standards of western medicine. To help manufacturers and distributors of dietary supplements better understand this phrase, the FDA developed a Background for Industry which states that manufacturers are “not limited in what evidence they may rely on in determining whether a new dietary ingredient is reasonably expected to be safe” (21). Manufacturers must provide a history of use or other evidence, and are responsible for determining what information provides the basis for their conclusion. There is an expectation, though not a requirement, that manufacturers consider evidence of safety found in the scientific literature, including an examination of adverse effects associated with the use of the substance. The complete guide is available at http://www.fda.gov/Food/DietarySupplements/ucm109764.htm.

**Legislative Differences Between Drugs and Dietary Supplements (3,13,18–21)**

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Dietary Supplements</th>
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<tbody>
<tr>
<td><strong>Formulation</strong></td>
<td>Drugs are available in a wide variety of forms including capsule, powder, softgel, gelcap, tablet, liquid, and others. Dietary supplements may be marketed in a variety of forms such as capsule, powder, softgel, gelcap, tablet, liquid, or, indeed, any other form so long as they are not represented as conventional foods or as sole items of a meal or of the diet (FDCA, as amended, § 402).</td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
<td>Drugs can be administered in a variety of ways including orally, parenterally, and topically. Dietary supplements must pass through the digestive system.</td>
</tr>
<tr>
<td><strong>Labeling</strong></td>
<td>Disease claims, which indicate a product can treat, prevent, cure, mitigate, or diagnose a specific disease, are reserved for drugs. Three types of claims are allowed for dietary supplements: structure/function claims, health claims, and nutrient content claims.</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>FDA requires premarket approval for drugs. Manufacturers are responsible for ensuring the safety of dietary supplement products; that supplement facts label and ingredient list are accurate; and that the content of the product matches the label.</td>
</tr>
<tr>
<td><strong>New Drug / New Ingredient Status</strong></td>
<td>FDA requires pre-market approval before new drugs can be marketed in the U.S. Dietary supplements cannot be a new drug or biologic prior to being marketed as a dietary supplement in the U.S., though products on the market prior to 1994 are exempt from this rule. Manufacturers must demonstrate (to FDA) that new ingredients used in supplements are “reasonably expected to be safe”.</td>
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Disputes between dietary supplement manufacturers and the FDA have challenged FDA’s ability to uphold DSHEA. An example of this is the interpretation of the prior market clause in DSHEA that precludes the use of approved drugs in dietary supplements unless those drugs were first marketed as food or dietary supplements. In the case of Pharmanex vs. Shalala, FDA argued that the relevant “article,” for purposes of excluding an ingredient, referred to the active pharmaceutical ingredient and not the actual ingredient or commerce used in the supplement. Pharmanex was the manufacturer of Cholestin, a red yeast rice supplement that contained several statins, including lovastatin, an active ingredient in the approved drug product Mevacor. The agency concluded that Pharmanex had taken several actions in the marketing and manufacturing of Cholestin that established lovastatin as the relevant “article” in the product rather than the red yeast rice. FDA based its conclusion on the fact that the firm manipulated the manufacturing process to induce lovastatin production, standardized its content in the product, and promoted its action in marketing the product. Pharmanex successfully argued in trial court that the relevant “article” was the article of commerce (i.e., the red yeast rice) rather than the active pharmaceutical ingredient it contained (i.e. lovastatin). Although the decision was reversed on appeal, it demonstrates some of the legal challenges FDA faces (25–26).

While the dietary supplement industry has not hesitated to challenge DSHEA, the FDA has used legislation in place to successfully remove products from the marketplace. FDA efforts, however, often take years and tax the agency’s resources at a time when demands on the FDA are increasing.

**Safety of Dietary Supplements**

When developing DSHEA, Congress believed that dietary supplements were safe within a broad range of intake. However, legislative pathways within FDA and the Federal Trade Commission (FTC) exist to address the potential for adverse events.

According to DSHEA, the government may take enforcement action against a dietary supplement or prohibit further manufacture of a dietary supplement when 1) the dietary supplement contains a substance that may injure health or an unapproved food additive not recognized as safe; 2) the dietary supplement poses significant risk of illness or injury; 3) the dietary supplement contains a new dietary ingredient for which FDA has not received notification; or 4) when the product does not meet good manufacturing practices (27–28). The FDA shoulders the burden of proof for demonstrating that a dietary supplement is not safe. In addition, enforcement action can also be taken against a dietary supplement for which disease claims are made.

DSHEA permits manufacturers of dietary supplements to make “structure/function” claims such as *promotes cardiovascular health*, but products including such claims must also include a disclaimer (cited above). In 2001, the FTC issued a guide to clarify FTC policies and enforcement practices related to dietary supplement advertising, available at www.ftc.gov/bcp/edu/pubs/business/adv/bus09.pdf (29).

**Recent Regulatory Initiatives**

In response to increasing numbers of reports of adverse effects related to the use of dietary supplements, two regulatory initiatives were recently implemented.

1. **Rules for Current Good Manufacturing Practices** (CGMP), went into effect in 2008. Under these rules, dietary supplement manufacturers are required to evaluate the identity, purity, strength, and composition of dietary supplements and follow guidelines for record keeping and handling consumer product complaints (30). In July 2009, the United States Pharmacopeia (USP) released a Dietary Supplements Compendium (DSC), designed to help manufacturers comply with current Good Manufacturing Practices (GMPs). Dietary supplement manufacturers must develop specifications for ingredients they include in products, and this compendium provides lists of quality specifications that manufacturers can use.

2. The **Dietary Supplement and Nonprescription Drug Consumer Protection Act** (AER Bill), requires manufacturers of dietary supplements...
and over-the-counter products to submit serious adverse event reports (31). This bill requires dietary supplement labels to list contact information for reporting adverse events. Companies must also notify FDA within 15 business days of receiving reports of serious adverse events. A serious adverse event is one which “results in death, life-threatening experience, inpatient hospitalization, disability or incapacity, surgical intervention, or congenital anomaly or birth defect, or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described” (31).

Neither of these initiatives address a major criticism of DSHEA, lack of pre-market approval of dietary supplements. However, they may allow the FDA to respond more quickly to emerging adverse events related to dietary supplements and promote standards that improve the quality of products produced.

**Do current regulations protect the public?**

In 1999, when testifying before the House Committee on Government Reform, Jane E. Henney, M.D., Commissioner of the FDA, stated “I think important progress has been made towards achieving the central objective of DSHEA: that of assuring consumer access to safe dietary supplements.” However, she voiced concern that a small but disturbing number of these products have a potential for harm or bear unsupported claims. She went on to state: “We are now engaged in the difficult task of delineating boundaries between drugs, dietary supplements, and conventional foods.” (32). Ten years later, this statement still reflects current dilemmas regarding dietary supplements.

Most Americans believe that dietary supplements are safe (33). However, since DSHEA became law in 1994 serious adverse events have been attributed to some dietary supplements, including Hydroxycut, Lipo-Kinetix, and dietary supplements that contain Chinese ephedra, a source of ephedrine alkaloids (34–36). A number of products have been associated with injury to the kidney (37). The 2002 Health & Diet Survey indicated that four percent of respondents who took dietary supplements reported at least one adverse event from their use. Consumers have reported gastrointestinal symptoms (nausea, abdominal pain, and diarrhea), cardiovascular symptoms (problems with chest pain and blood pressure), allergy symptoms (including rashes and itching), and general complaints such as dizziness (16).

Most adverse effects are associated with herbal and botanical dietary supplements. There is a large body of research, including randomized clinical trials, indicating safe and effective intake ranges for vitamins and minerals, and Upper Intake Levels have been established that identify highest intakes associated with minimal health risk. When vitamin and mineral supplements are used according to recommendations set forth in the Dietary Reference Intakes (DRIs) published by the Institute of Medicine (IOMs) there is minimal risk of adverse effects.

Botanicals that are sources of ephedrine alkaloids are frequently cited as examples of gaps in DSHEA that limit the FDA’s ability to remove potentially unsafe dietary supplements from the marketplace. Ephedrine alkaloids have sympathomimetic actions in the body that put an individual at risk of stroke and cardiac arrhythmia. Numerous deaths have been attributed to dietary supplements that contain botanical sources of ephedrine alkaloids (e.g., Ephedra) (34). After years of receiving complaints, the death of a professional baseball pitcher who reportedly took an ephedrine alkaloid-containing dietary supplement for weight loss prompted FDA action. In 2004, the FDA advised consumers to immediately stop taking any dietary supplements that contained ephedrine alkaloids and banned ephedrine alkaloids from the marketplace. However, legal challenges delayed final resolution of this issue until 2007. Other examples of dietary supplements receiving attention include Bitter Orange (Citrus aurantium L), which can reportedly increase blood pressure and induce cardiac arrhythmia (38) and Kava Kava, which has been banned in Europe and Canada because of case reports associating it with liver damage (39).

Reports of contamination have raised questions about quality control of dietary supplements. One case report involved possible arsenic toxicity in a woman taking a kelp supplement. Her arsenic levels returned to normal after she stopped using the dietary supplement. Following up on this case, FDA found that eight of nine kelp samples obtained from health food stores had arsenic levels greater than allowed, though labels did not warn consumers of the possibility of contamination (40).

Labels on dietary supplements are required to provide truthful information so consumers understand exactly what they are consuming. However, when interviewed for the article “Cancer and Supplements: What Vitamins, Herbs, and Botanicals Can (and Can't) Do”, the president of ConsumerLab.com reported that approximately 25 percent of supplements tested do not contain the claimed amount of a key ingredient, are not readily absorbed by the body, and are not free of harmful contaminants (41).

A 2009 report published by ConsumerLab indicated that five dietary supplements sold for bone health (of 22 tested) provided from 52.5% to 89% of the amount of calcium and vitamin K listed on the label (42). Another review found that approximately 30% of multivitamins tested contained doses significantly above or below levels indicated on the label, including 3 of 4 multivitamins sold for children which provided more than the Upper Intake Level for vitamin A (43). ConsumerLab and several independent organizations post “seals of approval” on packaging labels that indicate a dietary supplement has passed quality tests for criteria such as potency and contaminants. “Seals of approval” do not mean that the dietary supplement is safe or effective, but they provide assurance that the dietary supplement was properly manufactured, contains the ingredients

*(Continued on next page)*
listed on the label, and does not contain harmful levels of contaminants. Organizations offering these programs include:

- U.S. Pharmacopeia dietary supplement verification program: http://www.usp.org/USPVerified/dietarySupplements/
- Natural Products Association TruLabel Program: http://www.naturalproductsassoc.org/site/PageServer?pagename=ic_bg_trulabel

**Consumer Education**

The AER bill should decrease the risk of dietary supplement contamination, but the examples cited above emphasize a need for consumer education. Congress also recognized this need, and established the Office of Dietary Supplements (ODS) in 1994. ODS was authorized by DSHEA to explore the role of dietary supplements in health care, fund and coordinate scientific research on supplements, and collect and compile research on supplements. ODS sponsors workshops and conferences on dietary supplements, and the ODS website offers a wealth of information, including fact sheets on vitamins, minerals, and dietary supplements for professionals and consumers at http://ods.od.nih.gov.

The National Center for Complementary and Alternative Medicine (NCCAM) of the NIH offers free toolkits for healthcare providers at http://nccam.nih.gov/timetotalk/backgrounder.htm that encourage discussion of complementary and alternative medicine (CAM) use, including the use of dietary supplements, with patients and clients (44). Another resource that addresses frequently asked questions about dietary supplements is available through the Consumer Healthcare Products Association (CHPA) @ http://www.chpa-info.org/printer.aspx?id=83 (45).

**Summary**

Foods, drugs, and dietary supplements influence metabolism and potentially interact with each other. Interactions can be additive (potentiating an effect), synergistic, or antagonistic. With more than 20,000 herbal and botanical dietary supplements, a multitude of vitamin and mineral dietary supplements, and numerous concentrates, metabolites, and extracts sold as dietary supplements in the United States, there is some cause for concern.

To limit the risk of adverse effects from these interactions, consumers should discuss use of dietary supplement with their physician and registered dietitian. Providing education on the safe use of dietary supplements should be an essential component of clinical nutrition care.

**How RDs Can Promote the Safety of Dietary Supplements**

RDs need to play an important role in promoting safe use of dietary supplements by incorporating dietary supplement assessment into the nutrition care process. RDs can assess 1) dietary supplement intake history 2) contraindications for dietary supplements; 3) use of functional foods, neuterapeutics, and fortified foods, and 4) nutrient deficiencies and excesses. This information will allow oncology RDs to educate cancer survivors about potential benefits and risks of dietary supplements. RDs can also educate clients about strategies to evaluate supplements marketed, and should communicate potential concerns about supplements with the health care team.

Oncology RDs need to remain up-to-date with evidence based recommendations and resources on dietary supplements and cancer, and knowledgeable about controversies such as whether consuming soy and soy products is appropriate during and after treatment for breast cancer. By incorporating assessment of dietary supplement use and need within the nutrition care process, RDs can help promote safe use of dietary supplements and best care practices.

Maureen Leser is editor of Oncology Nutrition Connection.

**Acknowledgement:**

Thanks to Constance J. Hardy, interdisciplinary scientist with the FDA, for reviewing this article.

Constance J. Hardy, MS, RD
Interdisciplinary Scientist
Office of Nutrition, Labeling, and Dietary Supplements
Food and Drug Administration
College Park, MD 20740

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FNCE 2009 NEWS!!!

The Oncology Nutrition Dietetic Practice Group is sponsoring two sessions at the 2009 Food & Nutrition Conference & Expo in Denver, CO. The first session will address guidelines for enteral and parenteral nutrition for cancer patients and the second will address palliative care, nutrition, and ethics.

Sunday, October 18th
1:00 to 2:30 p.m.
Revised Guidelines for Enteral and Parenteral Nutrition for Cancer Patients

CPE Level: II  CPE Credit: 1.5  LNC: 5090, 5150, 5440

Presenting:
Maureen Huhmann, RD, DCN, CSO and David August, MD

Ms Huhmann and Dr. August have collaborated on numerous book chapters and articles about nutrition interventions used to treat, palliate, and support cancer patients, including Nutritional Care of Cancer Patients, a chapter in the book Surgery: Basic Science and Clinical Evidence (2008) and Nutrition in Gastrointestinal Cancer, a chapter in Nutrition and Gastrointestinal Disease (2008). They most recently collaborated on Surgical Oncology, a chapter in the book Clinical Nutrition for Oncology Patients (2009).

In their review article Nutrition Support in Surgical Oncology, published in Nutrition in Clinical Practice in 2009, they evaluated the evidence related to a highly debated topic, the use of nutrition support in surgical oncology patients. National guidelines have been published regarding the use of nutrition support in cancer patients, and these recognized experts, who were involved in recent revisions to these guidelines, will discuss these changes at FNCE. Their presentation has three main objectives.

Objective 1:
Discuss the role of nutrition support in cancer patients receiving chemotherapy.

Objective 2:
Identify appropriate use of enteral nutrition in cancer patients receiving radiation.

Objective 3:
Describe appropriate use of parenteral and enteral nutrition in surgical cancer patients.

Dr. August is Associate Professor, Chief, Division of Surgical Oncology, Department of Surgery, University of Medicine and Dentistry of New Jersey (UMDNJ), Robert Wood Johnson Medical School, and the Cancer Institute of New Jersey, New Brunswick, New Jersey, USA. He received his undergraduate degree in Life Sciences from the Massachusetts Institute of Technology. He trained in General Surgery at Yale-New Haven Hospital and in Surgical Oncology at the National Cancer Institute before coming to Yale Medical School as a faculty member. After spending five years on the faculty at the University of Michigan Medical School, Dr. August returned to the East Coast in 1994 to assume his current position at the Cancer Institute of New Jersey (CINJ). Dr. August has a longstanding interest in nutrition support of hospitalized patients, and is the author of over 70 journal articles and book chapters. A member of the Society of University Surgeons, the Society for Surgical Oncology, and the American Society for Parenteral and Enteral Nutrition, Dr. August is currently engaged in a variety of studies that look to optimize the use of nutritional substances in patient care and disease prevention.

Maureen Huhmann, DCN, RD, CSO, is a clinical dietitian at The Cancer Institute of New Jersey in New Brunswick and an assistant professor at the UMDNJ School of Health Related Professions. While her work at CINJ focuses on how nutrition complements a cancer patient’s treatment, she is also often called upon to lend her expertise to what role nutrition plays in the prevention of cancer. Dr. Huhmann has worked with participants of the Bridge Program at The Cancer Institute of New Jersey, which provides long-term wellness care, evaluation, support and health education for adult cancer survivors. A member of the American Dietetic Association and the Oncology Nutrition and Dietitians in Nutrition Support dietetic practice groups, Dr. Huhmann has published articles in peer-reviewed newsletters such as Oncology Nutrition Connection, the newsletter Health News Today, and numerous professional nutrition journals and textbooks. While Dr. Huhmann has a special interest in research and nutrition support, she is also a dedicated clinician. In 2006, Dr. Huhmann was recognized by the American Dietetic Association as the Young Dietitian of the Year for her work in nutritional care, and she is the current chair of the Oncology Nutrition Dietetic Practice Group of the American Dietetic Association.
Presenting:
Anne Cox, MS, RD and Ira Byock, MD

The Oncology Nutrition Dietetic Practice Group (ON DPG) is committed to providing resources and networking opportunities that help members manage the complexities of oncology practice. Consistent with this goal, ON DPG is pleased to announce that Anne Cox, MS, RD, and Ira Byock, MD, president of the American Academy of Hospice and Palliative Medicine, will discuss palliative care, nutrition, and ethics end-of-life care at the 2009 ADA Food & Nutrition Conference & Expo in Denver, Colorado.

Oncology dietitians are frequently involved in the care of patients with a terminal prognosis, and palliative therapy is often begun while patients are pursuing curative treatment. Management of nutrition-related symptoms such as nausea, vomiting, constipation, and bowel obstruction continue to be of prime importance towards the goal of quality of life. The transition away from curative modalities is different for every patient, and involves psychosocial and spiritual dimensions, posing a challenge to the dietitian involved in the plan of care, especially since aggressive efforts at repletion at this stage can detract from quality of life. Nutrition intervention is frequently considered by clinicians to be no longer important in the terminal stage of a patient’s life. However, patients and families do not echo this sentiment. Palliative Care is far from a “do nothing” concept – instead, it is “active total care”. The expertise of the dietetic professional therefore enables timely and appropriate nutrition intervention as part of the interdisciplinary team in accordance to diagnosis, stage of illness, and always in accordance to patient wishes. Ethical issues involving food and fluids require a sound knowledge of basic principles, advance directives, legal precedence, institutional policy, empathy and sensitivity in order to be an effective advocate of patient autonomy in the interrelationships with clinicians, patient and caregivers.

For the physician, medical end-of-life issues need to incorporate the personal realm inclusive of autonomy, privacy and intimacy. It is within this context that during his residency Ira Byock, MD, founded a hospice home care program for the indigent population of Fresno, California, beginning a lifelong commitment to the voices and rights of dying patients and their families. Dr. Byock has stated that “dying is a multidimensional, multifactorial experience for the person whose life is ending.” As such, “...care for people who are dying is organized around two major goals—alleviation of suffering and the enhancement of the person’s and family’s ongoing quality of life”. Widely recognized for his work in hospice care, Dr. Byock has published several articles on food and fluids at end of life based on his experience and research, encompassing physiological, legal, psychosocial and spiritual dimensions. During the 1990s, he was a co-founder and principal investigator for the Missoula Demonstration Project, a community-based organization in Montana dedicated to the research and transformation of end-of-life experience locally, as a demonstration of what is possible nationally. From 1996 through 2006, he served as Director for Promoting Excellence in End-of-Life Care, a national grant program of the Robert Wood Johnson Foundation.

Hired by a home hospice agency in 1995 as a hospice dietitian to satisfy regulatory requirements, Anne Cox, MS, RD, had limited knowledge of end-of-life care and how to meet the needs of dying patients. Using Nutritional Needs of the Terminal Patient by Charlotte Gallagher-Allred, RD, PhD, as a guide, she began carving a role as part of the interdisciplinary team. Recognizing the void in nutrition-related resources for dying patients, she sought out Ms. Gallagher-Allred at FNCE 1995, who encouraged her to begin a subunit under the Oncology Nutrition Dietetic Practice Group to unite the sparse number of hospice dietitians for the purpose of support and learning from each other. The terminal diagnosis of her 14-year-old son added another element to her “internship,” as she became both the dietitian and the caregiver of a dying child and experienced the impact of the hospice team’s intervention in meeting the needs of her son, herself, husband, and her 7 other children. The personal experience, grief journey, and gratitude of what the hospice team offered heightened her understanding of the patients she served, while bringing new determination to develop nutrition resources towards the goal of standardized palliative nutrition therapy. This FNCE End of Life Session featuring Ira Byock is part of that vision to provide means for any dietitian involved with terminal patients to be as effective as possible in caring for the nutritional need of the dying. The upcoming ADA Pocket Guide of Nutrition in Hospice & Palliative Care that she is currently working on as co-editor and author will serve to further that vision.

Please join us in Denver to hear Ms Cox’s and Dr. Byock’s perspectives on palliative care, nutrition, and ethics.
Weight Loss in Ambulatory Cancer Patients Prior to Initiation of Home Parenteral Nutrition

Denis Knobel, MD  Rafael Barrera, MD  Natalie Gabovich, MD  Carol Ireton-Jones, PhD, RD, CNSD, FACP

Abstract
Malnutrition among patients who have chronic conditions has been associated with increased morbidity, mortality, and overall cost of care (1,2). The indication for HPN in cancer patients is multifactorial. Intestinal failure and malnutrition are two problems seen in cancer patients that influence survival. In an effort to improve the nutritional status of such patients, we evaluated a series of demographic and nutritional characteristics that might predict a possible benefit of home parenteral nutrition (HPN) when initiated prior to severe weight loss. Patients were followed for 12 months. A total of 96 outpatients were evaluated, of whom 58 cancer patients had weight loss greater than 10% (mean of 20.0%) and 38 cancer patients had weight loss less than 10% (mean of 4.9%). The mean percent weight loss was 13.7%±11.4% (95% confidence interval [CI] 11.4% to 16.0%). The mean age of patients was 58.4 years (standard deviation [SD] 12.4 years). There was no significant difference in age and sex between the two cancer groups. Patients for whom HPN was started before weight loss of 10% were able to gain back their usual body weight by 3 months. Patients who lost more than 10% of their usual body weight before initiating HPN were able to regain only 83% of their usual body weight. Patients in the group that lost less than 10% of weight prior to starting HPN reached a maximum Karnofsky performance status of 80% within 2 months. Patients in the group with severe weight loss were only able to reach a maximum Karnofsky performance status of 70%. HPN is a tool for keeping patients at home and maintaining quality of life in most patients treated for a short period of time.

Introduction
Malnutrition among patients who have chronic conditions, such as short bowel syndrome (SBS), intestinal failure, and cancer, has been closely associated with increased morbidity, mortality, and overall cost of care (1,2). The indication for HPN in cancer patients is multifactorial. Intestinal failure and malnutrition are two problems seen in some cancer patients that influence survival. Guidelines for HPN in cancer patients are still controversial, but some criteria for initiating HPN have been suggested (3–7):

1. Cancer patients who have bowel obstruction, SBS, or malabsorption, where it seems probable that death by starvation or malnutrition would ensue much earlier than death from disease progression and enteral nutrition is not an option.
2. A life expectancy of some months and duration of HPN treatment expected to be at least 6 weeks.
3. High quality of life.
4. Sufficient functional status and home environment for PN to be instituted and monitored successfully; the patient’s physical function should be sufficient, as reflected by a Karnofsky score greater than 50.

Certain successes have been recorded when these guidelines were applied. Bozzetti and associates (8) described a prospective observational study in which 38% of the study group patients experienced prolonged survival with PN. These patients were able to achieve stability of quality of life indices while receiving HPN. The authors concluded that HPN should be administered to patients whose Karnofsky performance status scores are greater than 50 and who have valid medical indications, a positive assessment of well-being and quality of life, and the expectation that PN could be continued for a trial of at least 1 month.

In an effort to improve the nutritional status of such patients, we evaluated a series of demographic and nutritional characteristics that might predict a possible benefit of HPN when initiated prior to severe weight loss, which was defined as weight loss greater than 10% of usual body weight over a 6-month period. (2)

Methods
This investigational study examined a prospectively collected database of 96 cancer patients from the clinical records of a home infusion provider over 1-year period. The data included sex, usual weight (which was defined as weight prior to diagnosis of cancer), body mass index (BMI), body weight at the start of HPN, and percent weight loss from usual weight prior to initiating PN. Patients were followed for 12 months. The primary indications for HPN were weight loss and intestinal obstruction (Fig 1). A series of demographic, Karnofsky performance, and nutritional characteristics were analyzed in an attempt to predict a possible benefit of HPN prior to severe weight loss.

Statistics
A Students t-test was employed to compare age, weight, and BMI. A chi square test was used to examine the percent weight loss among the different groups of patients. Data are presented as mean ± SD. Statistical significance was considered at a P<0.05.

Results
A total of 96 outpatients were evaluated, of whom 58 cancer patients had weight loss greater than 10% (mean of 20.0%) and 38 cancer patients had weight loss less than 10% (mean of 4.9%) (Fig 2). The mean percent weight loss was 13.7%±11.4% (95% CI, 11.4% to 16.0%). The mean age of patients was 58.4 years (SD 12.4 years). There was no significant difference in age and sex between the two cancer groups (Table). The mean daily energy intake of both...
groups was 1,811±477 kcal. The energy intake was 4.8% less than the recommended daily intake of 1,895±370 kcal (95% CI, 0.28 to 9.32), which was calculated using the Harris-Benedict equation (2). Four patients were receiving enteral feedings in addition to the PN. Patients in whom HPN was started before weight loss of 10% were able to gain back their usual body weight by 3 months. In that same time period, patients who lost more than 10% of their usual body weight before initiating HPN were only able to regain 83% of their usual body weight.

When evaluating weight loss related to Karnofsky performance status, 65.8% of cancer patients who lost less than 10% of their usual body weight before initiation HPN had Karnofsky performance status greater than 50, compared with 98.3% of the cancer patients who lost more than 10% of their usual body weight before starting HPN (P=0.0001) (Table). Despite the presence of fewer patients with Karnofsky performance status greater than 50 in the patient group that had less severe weight loss, these patients attained improved Karnofsky performance status in a shorter period of time than the group that experienced severe weight loss. Patients in the less severe weight loss group reached a maximum Karnofsky performance status of 80% in 2 months compared with achievement of a Karnofsky performance status of 64% among those who had severe weight loss in the same time period (P=0.071). Overall, patients in the group that received HPN initiated before a weight loss of 10% were able to gain weight to their usual body weight. All of the patients improved their Karnofsky performance scores, despite one third of patients having scores less than 50 at the start of the HPN.

Discussion
PN is a life-saving treatment for many cancer patients. HPN allows patients to spend more time at home, with stable quality of life. (9,10) Cancer patients who are candidates for HPN have disabling consequences of cancer therapies, such as radiation enteritis, SBS, or gastrointestinal fistulas after surgery, which sometimes result in intestinal failure. Malnourished or hypophagic patients for whom nutrition support is necessary to improve their compliance with chemotherapy or radiation therapy also are candidates for HPN (5,6). Patients who have advanced disease and whose survival is affected more by their poor ability to receive nourishment due to chronic intestinal obstruction or pseudo-obstruction, neoplastic fistulas, or nutrition-related pain than by the progressive involvement of vital organs benefit from this therapy (4). The challenge in providing nutrition support to cancer patients is recognizing the malnourished state and the need for HPN prior to significant weight loss. This study demonstrates that HPN can benefit patients with cancer if it is not delayed until significant weight loss has occurred. Weight loss of more than 10% over 6 months has been associated with an increased risk of morbidity and mortality, regardless of the underlying disease state (2). In addition, the adverse impact of weight loss has led to increased frequency of hospitalizations and cost of care in many cases (11). HPN has been shown to be a safe approach to improving nutritional status and achieving a better quality of life while allowing patients to remain at home (12,13). Our results showed that patients who had HPN started before severe weight loss were able to regain their usual body weight and to improve their Karnofsky performance status in a shorter period of time. This outcome is positive, even though statistical significance was not reached between the two groups.

Conclusion
HPN can benefit or at least maintain nutritional status and quality of life in most patients treated for a short period of time. Furthermore, our analysis points (Continued on next page)
toward the need for further development of HPN guidelines for cancer patients and the importance of initiating HPN before severe weight loss occurs.

The authors recognize the significant contributions of Dr. Donald Kirby in the development and review of the study protocol and the dietitians and clinicians at Coram Healthcare, who collected the patent data for this study.

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Carol Ireton-Jones, PhD, RD, CNSD, FACN, with Professional Nutrition Therapists, LLC, also is a consultant for Coram Specialty Infusion, an Apria Healthcare Company, Denver, CO.

### References


### Table. Demographic Characteristics

<table>
<thead>
<tr>
<th>Weight Loss Less Than 10%</th>
<th>Severe Weight Loss</th>
<th>All</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>38</td>
<td>58</td>
<td>96</td>
</tr>
<tr>
<td>Age (SD)</td>
<td>59.9 (11.6) years</td>
<td>58.0 (12.9) years</td>
<td>58.0 (12.0) years</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>27</td>
<td>31</td>
<td>58</td>
</tr>
<tr>
<td>Male</td>
<td>11</td>
<td>27</td>
<td>38</td>
</tr>
<tr>
<td>Albumin (SD)</td>
<td>3.0 (0.6) g/dL</td>
<td>2.9 (0.5) g/dL</td>
<td>3.0 (0.6) g/dL</td>
</tr>
<tr>
<td>Mean daily energy intake</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommended (SD)</td>
<td>1,820 (413) kcal</td>
<td>1,938 (339) kcal</td>
<td>1,895 (370) kcal</td>
</tr>
<tr>
<td>Actual (SD)</td>
<td>1,740 (524) kcal</td>
<td>1,853 (447) kcal</td>
<td>1,811 (477) kcal</td>
</tr>
<tr>
<td>Number of patients with Karnofsky score &gt;50</td>
<td>65.8%</td>
<td>98.3%</td>
<td>64.6%</td>
</tr>
</tbody>
</table>
The spring issue of Oncology Nutrition Connection brought you a scientific review of tea and cancer prevention. However, it is also important for oncology dietitians to be familiar with tea beverages sold for cancer prevention that may not have scientific support.

**Kombucha tea** is a beverage produced by fermenting sweetened black or green tea with a fungus (kombucha). After one to several weeks of fermentation, a sac that resembles a mushroom forms on top (1). Promoted as a treatment or cure for a wide variety of conditions, including hypertension, acne, arthritic pain, constipation, HIV, and cancer, its popularity in the United States is increasing. There are no human studies that document its health effects, either positive or negative (2). However, there are numerous case reports of adverse effects. In 1995, two women were hospitalized after drinking kombucha tea regularly for several months. One of these women, who had increased her daily intake to 12 ounces, died of cardiac complications (3). A 2009 case report described a 22-year-old HIV+ male who became short of breath and febrile, and required intubation for airway control within twelve hours of drinking Kombucha tea (4). Case reports of allergic reactions, stomach upset, and jaundice have also been published (1–3,5).

Kombucha contains a variety of yeast and bacteria, including Saccharomyces ludwigii, Schizosaccharomyces pombe, Brettanomyces bruxellensis, bacteriums from xylinum, gluconicum, xylinoides, and katogenum, Pichia fermentans, Candida stellata, and Torula (1). It is sold commercially, but many people make their own at home. When prepared as usually directed, the pH of the tea may drop to as low as 1.8. This level of acidity limits growth of most contaminating organisms, but there are reports that molds sometimes grow on the mushroom. After the tea is fermented, this highly acidic beverage contains alcohol, ethyl acetate, acetic acid, and lactate (6). Proponents advise a gradual increase in intake, starting with only 1 to 2 ounces daily.

The American Cancer Society [http://www.cancer.org/docroot/ETO/content/ETO_5_3X_Kombucha_Tea.asp](http://www.cancer.org/docroot/ETO/content/ETO_5_3X_Kombucha_Tea.asp), Mayo Clinic [http://www.mayoclinic.com/health/kombucha-tea/an01658](http://www.mayoclinic.com/health/kombucha-tea/an01658), and the Center for Disease Control and Prevention [http://www.cdc.gov/mmwr/preview/mmwrhtml/00039742.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/00039742.htm) have posted statements on their websites warning consumers of potential adverse effects of kombucha tea.

**RDS need to be aware that:**
Available scientific evidence does not support claims that Kombucha tea promotes good health, prevents any ailments, or is effective in treating cancer or any other disease.

Potential adverse health effects of kombucha tea include:
- **Metabolic Acidoses** can result from drinking large quantities of this highly acidic beverage. Patients with unexplained lactic acidosis should be questioned about their use of kombucha tea.
- **Contamination** may occur if not prepared under sterile conditions.
- When brewed or stored in lead based ceramics, the acidity of the tea can cause lead to leach into the beverage and result in lead toxicity or poisoning.
- **Stomach upset** has frequently been reported after drinking kombucha tea.

RDs who discover from patient report that drinking kombucha tea has resulted in adverse health effects should file a report with FDA’s MedWatch program (800-332-1088 or 301-738-7553).

**References and Resources:**
1. [http://www.cancer.org/docroot/ETO/content/ETO_5_3X_Kombucha_Tea.asp](http://www.cancer.org/docroot/ETO/content/ETO_5_3X_Kombucha_Tea.asp)
3. [http://www.cdc.gov/mmwr/preview/mmwrhtml/00039742.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/00039742.htm)
ON DPG Member Spotlight

Elaine B. Trujillo, MS, RD, obtained her Bachelor of Science degree in nutritional science at the University of Delaware. After graduation Elaine moved to Texas, where she completed her studies for a Master of Science degree in nutrition and a dietetic internship at Texas Woman’s University. Elaine then began her professional career at St. Luke’s Episcopal Hospital in Houston, Texas, where she provided nutritional care for surgical, gastrointestinal, cardiovascular, and maternity patients. Early in her career Elaine also began mentoring students, which evolved into a lifelong commitment to fostering the professional growth and development of dietetic interns and nutrition students.

In 1989, Elaine moved north to Boston, Massachusetts, obtaining a position as a clinical dietitian at Beth Israel Deaconess Hospital. For three years, Elaine managed the nutritional care of critically ill surgical patients and gastrointestinal and liver transplant patients. She served on the liver transplant team, and became involved in implementing the hospital’s first Enteral Nutrition Service. A few years later, Elaine accepted a position at the Brigham & Women’s Hospital in Boston, where she continued to specialize in nutrition support but also expanded her nutrition practice to research. Working with their metabolic support service, Elaine had the opportunity to design, organize, and manage clinical nutrition research studies. She provided nutrition support resources for physicians, nurses, students, staff dietitians, and other health care professionals. Committed to expanding the role of the R.D. and nutrition services within the hospital, Elaine became associate editor of the department newsletter, Nutriture, and became involved in weight management treatment, counseling patients and leading support groups for overweight patients. She also continued to precept dietetic interns.

After 10 years in Boston, Elaine and her family relocated to the Washington, DC. area. Elaine worked as a cardiac rehab dietitian before joining the National Cancer Institute (NCI), National Institutes of Health (NIH), in Rockville, Maryland. Her move to the Division of Cancer Prevention within the NCI has allowed her to devote more time to the field of oncology nutrition, where she serves as liaison between the Oncology Nutrition Dietetic Practice Group and the National Cancer Institute. For the past five years, Elaine has developed and managed a unique program that provides training in oncology nutrition research for registered dietitians (RDs), dietetic interns, professors, graduate nutrition students, and other healthcare professionals. Elaine has also been instrumental in organizing the bi-annual Stars in Nutrition and Cancer lecture series at the NIH, which allows extraordinary contributors or “Stars” in the field to highlight the importance of nutrition in cancer research. As a nutritionist with the NCI, Elaine reviews and interprets complex nutrition data for inclusion in reports and fact sheets, promotes programs, ensures the agency position is considered in policy, and serves as a technical resource on a broad range of nutrition activities. Elaine also represents the NCI on the NIH Nutrition Education Subcommittee, a subcommittee of the Nutrition Coordinating Committee charged with reviewing nutrition education materials developed throughout the NIH.

Elaine is an accomplished author and presenter. Her publications include contributing chapters to the 1998 and 2005 A.S.P.E.N. Nutrition Support Manuals and a chapter on Parenteral Nutrition in 2009 Conn’s Current Therapy. Working with a cookbook author and chef, Elaine developed and published a nutrition cookbook, Eating for Lower Cholesterol: A Balanced Approach to Heart Health with Recipes Everyone will Love, while working at Shady Grove Hospital as a cardiac rehabilitation RD. She has presented on topics as diverse as nutrition support and assessment for a variety of diagnoses, wound healing, and the immune suppressed patient, and developed a Handbook on Enteral Nutrition for nutrition professionals. A burgeoning interest in nutrigenomics inspired Elaine to submit the article Nutrigenomics, proteomics, metabolomics and the practice of dietetics to the Journal of the American Dietetic Association, for which Elaine won the ADA’s Huddleson Award in 2007 for making an important contribution.
Elaine is an RD and LD in the state of Maryland, and is a member of the American Dietetic Association (ADA) and the ON DPG. Elaine was recently appointed Chair of the Education and Research Division of the Maryland Dietetics Association. Elaine is also a wife and proud mother of two teenagers. She loves to read and travel, and frequently travels with her family to Puerto Rico, where her husband was raised. Elaine has presented several nutrition programs there, and appreciates the value of her diverse experiences. Elaine also has a black belt in martial arts.

ON DPG congratulates Elaine on her dedication to dietetics and her work with NCI furthering the role of RDs in oncology nutrition practice.

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- Nominating Committee Chair

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