American Academy of Sports Dietitians and Nutritionists

Endorsement and Sale of Nutritional Supplements

ABSTRACT

Allied health and fitness professionals are aware that the endorsement or sale of prescription and over-the-counter medications is beyond their scope of practice. What is not clear is their role in the endorsement or sale of nutritional supplements. Marketing by the supplement industry has convinced health professionals and consumers that supplements, unlike drugs, have no side effects, are "all natural" and are therefore "safe". However, consumers are ingesting combinations of supplements, supplements with prescription and non-prescription drugs, without any regard to side effects, interactions and complications. The Dietary Supplement Health and Education Act (DSHEA) was unanimously signed by Congress in October of 1994.[1] The FDA notes that under the DSHEA law supplements are no longer regulated like other products such as drugs, additives, cosmetics, foods (animal and human), medical devices, and radiation emitting consumer products (microwaves).[2] Supplement manufacturers are not held to any rigorous standards, and according to a survey of physicians—orthopedic surgeons, rheumatologists and sports medicine practitioners—60 percent of those polled felt there was not enough FDA oversight of the dietary supplement industry to warrant recommending supplements.[3] Therefore, it is the position of the American Academy of Sports Dietitians and Nutritionists (AASDN) that endorsement or sale of nutritional supplements by allied health and fitness professionals constitutes an unsafe practice and is in violation of the professional code of conduct held by all health and fitness professionals to "do no harm". Endorsement or sale of nutritional products must come directly from the consumer's physician or a Registered /Licensed Dietitian.

This position paper reviews the current scientific data relating to the safety and efficacy of supplements (any product that contains vitamins, minerals, herbs or other botanicals, amino acids, enzymes, and/or other ingredients intended to supplement the diet)[1] in the United States and the role of allied health and fitness professionals in the endorsement and sale of these products.

It is the position of the AASDN that the endorsement or sale of nutritional supplements by allied health and fitness professionals constitutes an unsafe practice and is in violation of the professional code of conduct held by all health and fitness professionals to "do no harm". Endorsement or sale of nutritional products must come directly from the consumer's physician or a Registered / Licensed Dietitian. Unqualified professionals, for safety reasons, must refrain from endorsement of or sale of nutritional supplements (any product that contains vitamins, minerals, herbs or other botanicals, amino acids, enzymes, and/or other ingredients intended to supplement the diet).[1]

INTRODUCTION

Allied health and fitness professionals (who are not licensed physicians or health care practioners) are aware that endorsement or sale of prescription and over-the-counter medications is beyond their scope of practice. What is not clear is their role in the endorsement or sale of nutritional supplements.

BACKGROUND

More than one half of the U.S. adult population use dietary supplements at a cost of $23 billion a year.[13] Many of these consumers are unaware of the changes associated with the manufacturing of supplements that began in 1994. Before 1994, the Food and Drug Administration (FDA) regulated supplements as foods to ensure that they were safe and wholesome. Ensuring safety involved evaluation of all new ingredients. In 1994 the Dietary Supplement Health and Education Act (DSHEA) was passed by Congress. With the passage of the DSHEA supplements were removed from regulation by the FDA. Also with the passage of DSHEA, the original definition of a supplement was changed from "a product that contained one or more of the essential nutrients" to "any product that contains vitamins, minerals, herbs or other botanicals, amino acids, enzymes, and/or other ingredients intended to supplement the diet".[1]

This statement was authored by the American Academy of Sport Dietitians and Nutritionists. Individual name recognition is reflected in the acknowledgments at the end of this document.

The FDA advises that consumers should know the following when considering using a dietary supplement.

•Federal law requires that every dietary supplement be labeled as such, either with the term "dietary supplement" or with a term that substitutes a description of the product's dietary ingredient(s) for the word "dietary" (e.g., "herbal supplement" or "calcium supplement").

•Federal law does not require dietary supplements to be proven safe to the FDA's satisfaction before they are marketed.

•For most claims made in the labeling of dietary supplements, the law does not require the manufacturer or seller to prove to the FDA's satisfaction that the claim is accurate or truthful before it appears on the product.

•In general, the **FDA's role with a dietary supplement product begins after the product enters the marketplace. That is usually the agency's first opportunity to take action against a product that presents a significant or unreasonable risk of illness or injury, or that is otherwise adulterated or misbranded.**

•Dietary supplement advertising, including ads broadcast on radio and television, falls under the jurisdiction of the of the Federal Trade Commission.

•Once a dietary supplement is on the market, the FDA has certain safety monitoring responsibilities. These include monitoring mandatory reporting of serious adverse events by dietary supplement firms and voluntary adverse event reporting by consumers and health care professionals. As its resources permit, the FDA also reviews product labels and other product information, such as package inserts, accompanying literature, and Internet promotion.

•Dietary supplement firms must report to the FDA any serious adverse events that are reported to them by consumers or health care professionals.

•Dietary supplement manufacturers do not have to get the agency's approval before producing or selling these products.

•It is not legal to market a dietary supplement product as a treatment or cure for a specific disease, or to alleviate the symptoms of a disease.

•There are limitations to the FDA oversight of claims in dietary supplement labeling. For example, FDA reviews substantiation for claims as resources permit.

SAFETY

Prescription and over-the-counter medications are regulated by the FDA. Most consumers are aware of the dangers associated with ingestion of these products.

What is not clear to consumers are possible dangers associated with ingestion of combinations of nutritional supplements; or interactions associated with ingestion of supplements in combination with prescription and over-the-counter medications.

The Food and Drug Administration (FDA) suggests that consumers consult with their health care professional before using any dietary supplement. Many supplements contain ingredients that have strong biological effects, and such products may not be safe in all people. [23]

Many dietary supplements have clean safety histories. For example, millions of Americans responsibly consume multi-vitamins and experience no ill effects. Some dietary supplements have been shown to be beneficial for certain health conditions. For example, the use of folic acid supplements by women of childbearing age who may become pregnant reduces the risk of some birth defects.

However, according to the FDA, if you have certain health conditions and take these products, you may be putting yourself at risk. [23] Here is some general advice from the FDA: [23]

•Dietary supplements are not intended to treat, diagnose, cure, or alleviate the effects of diseases.

•They cannot completely prevent diseases, as some vaccines can. However, some supplements are useful in reducing the risk of certain diseases and are authorized to make label claims about these uses. For example, folic acid supplements may make a claim about reducing the risk of birth defects of the brain and spinal cord.

•Using supplements improperly can be harmful. Taking a combination of supplements, using these products together with medicine, or substituting them in place of prescribed medicines could lead to harmful, even life-threatening, results.

•Some supplements can have unwanted effects before, during, or after surgery. For example, bleeding is a potential side effect of garlic, ginkgo biloba, ginseng, and Vitamin E. In addition, kava and valerian act as sedatives and can increase the effects of anesthetics and other medications used during surgery. Before surgery, you should inform your health care professional about all the supplements you use.

Some supplements have had to be recalled because of proven or potential harmful effects. Reasons for these recalls include:

•microbiological, pesticide, and heavy metal contamination
•absence of a dietary ingredient claimed to be in the product
•the presence of more or less than the amount of the dietary ingredient claimed on the label

In addition, unscrupulous manufacturers have tried to sell bogus products that should not be on the market at all.

Experts Weigh In!

"There are no requirements for supplement manufacturers to prove that their products are safe", says Robert Parks, Author of *Voodoo Science – the Road from Foolishness to Fraud*. DSHEA is his candidate for the worst piece of legislation ever passed.[4] According to Parks:

> "Supplement manufacturers are not held to any rigorous standards. Before 1994 manufacturers had to prove that their product was safe or at least that what you said on the label was in the bottle".
>
> "Manufacturers don't have to do that anymore," states Mr. Parks. "Under DSHEA testing is voluntary. It's wonderful right now for companies that make supplements. I would not be regulated. The only people I would have to answer to is my stock holders to see how much profit I am making. The FDA can only step in when the supplement has been shown to be unsafe." [4]

Tests performed by ABC's TV program 20/20 on over 100 bottles of supplements found that one in four did not have what the manufacturer stated on the label. Dr. Todd Cooperman of consumerlab.com provided the detailed analysis for the 20/20 investigation. According to Dr. Cooperman, the only way to know what's in a supplement pill is to test it. [11]

The 20/20 investigation centered on three popular supplements: Chondroitin, SAM-e, and ginseng. Eight of the 15 bottles of chondroitin tested, failed – they did not have the amount that was stated on the label. Four bottles had less than 10% of what was stated on the label. To everyone's surprise, some of the most expensive brands of chondroitin had the least amount. Six of the thirteen bottles of SAM-e tested, failed. Most had less than half the amount listed on the bottle. One bottle had no SAM-e.

Consumerlab.com tested SAM-e three times, in three different labs, using three different methods to be sure they weren't making a mistake. And five out of twenty-one bottles of ginseng tested, failed. EIGHT BOTTLES HAD QUINTOZENE in them, A PESTICIDE SPRAYED ON THE PLANT WHEN IT IS GROWING. [11]

It's not just consumerlab.com that found problems. The Good Housekeeping Institute tested SAM-e, Consumer Reports tested echinacia, and the Los Angeles Times tested St. John's Wort. All reported that what was stated on the label was not always in the bottle. According to Dr. Cooperman, until someone is checking the industry there is no incentive to fix the problem. [11]

"Dietary supplements are the ultimate merger of self-improvement and free enterprise, with the promises and pitfalls of both", says Jeff O'Connel, author of *Beyond Balco: The Untold Dietary Supplement Scandal*. "When you purchase that bottle of pills or canister of powder, you may be walking out with a useful concoction or the equivalent of sawdust — or something truly harmful." [12]

According to a survey of physicians—primarily orthopedic surgeons, rheumatologists and sports medicine practitioners—60 percent of those polled felt there was <u>not</u> enough FDA oversight of the dietary supplement industry to warrant recommending supplements. [3]

According to Dr. Joe Graden, pharmacologist and radio talk show host of the People's Pharmacy, "people are popping pills and they don't know what they're getting into. People think it's natural, how bad can it be? But supplements are chemicals just like drugs; in overdose they can cause side effects just like drugs; in wrong combinations they can cause complications, just like drugs. Your body can't tell the difference". "It's like a wild west show", explains Dr. Graden. "Supplement manufacturers can get away with anything and many of them do".[4]

All Natural

The USDA has a legal definition for "natural", but it applies only to meat and poultry: Those meat and poultry products carrying the "natural" claim must not contain any artificial flavoring, color ingredients, chemical preservatives, artificial or synthetic ingredients, and are only "minimally processed" defined by the USDA as a process that does not fundamentally alter the raw product." [6]

Consumers Union, publisher of Consumer Reports, which is an independent, nonprofit testing and information organization serving only consumers, states:

> "Natural is a general claim that implies that the product or packaging is made from or innate to the environment and that nothing artificial or synthetic has been added. **There is currently no standard definition for the term except for meat and poultry products.** Unless otherwise specified, there is no organization independently certifying this claim. The producer or manufacturer decides whether to use the claim and is not free from its own self-interest." [7]

"Defining natural is very difficult and messy," said Michael Jacobson, executive director of the non-profit Center for Science in the Public Interest. Indeed, everything from soda pop to potato chips has been marketed as natural. Jacobson's group, which tracks food labeling and nutrition issues, at least thinks it knows when a product is **not** natural and it's taken to task companies it believes are misusing the natural label, including Cadbury Schweppes. [8]

Center for Science in the Public Interest also sued Kraft for marketing its Capri Sun beverage as all-natural. The suit was dropped after Kraft said it was reformulating Capri Sun and dumping the all-natural phrase. High-fructose corn syrup, a key ingredient in Capri Sun, was the critical element in the dispute, as it has been in several other suits over natural claims.

Jacobson's group argues that while corn is natural, high-fructose corn syrup is man-made. The sugar industry, the corn-sweetener business' main rival, not surprisingly agrees. A big fight over the issue is pending before the FDA. [9]

The term "natural" is not to be confused with "organic," a designation that is defined in much more detail by food regulators. USDA rules implemented in 2002 lay out specific production methods for foods to be called organic. The USDA National Organic Program defines non-synthetic as "a substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process". They define a synthetic as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes." [10]

FRADULENT PRACTICES

According to the FDA, consumers also need to be on the lookout for fraudulent products. These are products that don't do what they say they can or don't contain what they say they contain. At the very least, they waste consumers' money, and they may cause physical harm.

Fraudulent products often can be identified by the types of claims made in their labeling, advertising and promotional literature. Some possible indicators of fraud, says Stephen Barrett, M.D., a board member of the National Council Against Health Fraud, are:

- Claims that the product is a secret cure and use of such terms as "breakthrough," "magical," "miracle cure," and "new discovery." If the product were a cure for a serious disease, it would be widely reported in the media and used by health-care professionals, he says.
- "Pseudomedical" jargon, such as "detoxify," "purify" and "energize" to describe a product's effects. These claims are vague and hard to measure, Barrett says. So, they make it easier for success to be claimed "even though nothing has actually been accomplished," he says.
- Claims that the product can cure a wide range of unrelated diseases. No product can do that, he says.
- Claims that a product is backed by scientific studies, but with no list of references or references that are inadequate. For instance, if a list of references is provided, the citations cannot be traced, or if they are traceable, the studies are out-of-date, irrelevant, or poorly designed.

•Claims that the supplement has only benefits--and no side effects. A product "potent enough to help people will be potent enough to cause side effects," Barrett says.
•Accusations that the medical profession, drug companies and the government are suppressing information about a particular treatment. It would be illogical, Barrett says, for large numbers of people to withhold information about potential medical therapies when they or their families and friends might one day benefit from them.

Though often more difficult to do, consumers also can protect themselves from economic fraud, a practice in which the manufacturer substitutes part or all of a product with an inferior, cheaper ingredient and then passes off the fake product as the real thing but at a lower cost. Varro Tyler, Ph.D., Sc.D., a distinguished professor emeritus of pharmacognosy (the study of medicinal products in their crude, or unprepared, form) at Purdue University in West LaFayette, IN, advises consumers to avoid products sold for considerably less money than competing brands. "If it's too cheap, the product is probably not what it's supposed to be," he says.

Poor manufacturing practices are not unique to dietary supplements, but the growing market for supplements in a less restrictive regulatory environment creates the potential for supplements to be prone to quality-control problems. For example, FDA has identified several problems where some manufacturers were buying herbs, plants and other ingredients without first adequately testing them to determine whether the product they ordered was actually what they received or whether the ingredients were free from contaminants.

To help protect themselves, consumers should:
•Look for ingredients in products with the U.S.P. notation, which indicates the manufacturer followed standards established by the U.S. Pharmacopoeia.
•Realize that the label term "natural" doesn't guarantee that a product is safe. "Think of poisonous mushrooms," says Elizabeth Yetley, Ph.D., director of FDA's Office of Special Nutritionals. "They're natural."
•Consider the name of the manufacturer or distributor. Supplements made by a nationally known food and drug manufacturer, for example, have likely been made under tight controls because these companies already have in place manufacturing standards for their other products.
•Write to the supplement manufacturer for more information. Ask the company about the conditions under which its products were made.
•Visit www.fda.gov/forconsumers/default.htm for updates on product recalls.

Known Interactions/Side Effects
Contrary to popular belief all chemicals whether drugs or supplements which have an effect in the human body produce side effects. Some side effects are well known and documented. However, without substantive research many unknown side effects and interactions can exist between different types of supplements and interactions between supplements with drugs; the dangers of which can range from mild to very serious.

For example, natural herbal supplements are supposed to help boost the immune systems, provide energy and increase general health. However, many of these supplements could cause dangerous side effects during plastic surgery, reports a study in February's Plastic and Reconstructive Surgery, the official medical journal of the American Society of Plastic Surgeons (ASPS). The study found approximately 55 percent of plastic surgery patients, compared to 24 percent of the general public, take supplements but often do not tell their surgeons. All 55 of plastic surgery patients who used herbal supplements took at least two different supplements and at least one supplement on a daily basis.

"When patients are asked about the medications they are taking, many do not mention medicinal herbs because they assume that they are safe," said ASPS member James Bradley, MD, study co-author, University of California, Los Angeles. "**What many unsuspecting patients don't know is that the natural herbs they are taking may cause serious complications during and after surgery**." Echinacea is often used for the prevention and treatment of viral, bacterial and fungal infections, as well as chronic wounds, ulcers and arthritis. However, it can trigger immunosuppression, causing poor wound healing and infection. Glucosamine, often offered in conjunction with chondroitin, contains chemical elements that mimic human insulin, and may artificially cause hypoglycemia during surgery. Chondroitin is often used to treat osteoarthritis. People using chondroitin may suffer from bleeding complications during surgery, particularly when used in combination with doctor-prescribed blood-thinning medications. Other common supplements taken by patients in the study that may cause dangerous side effects included gingko biloba, goldenseal, milk thistle, ginseng, kava and garlic. The most popular herbal supplements were chondroitin (18 percent), ephedra (18 percent), echinacea (14 percent) and glucosamine (10 percent).

Ephedra has been known to promote weight loss, increase energy and treat respiratory tract conditions such as asthma and bronchitis. This agent has been banned by the U.S. Food and Drug Administration (FDA) because it can raise blood pressure, heart rate and metabolic rate, ultimately causing heart attacks, heart arrhythmia, stroke and even death.

EFFICACY

"I'm puzzled why the public in general ignores the results of well-done trials," said Dr. Eric Klein, national study coordinator for the prostate cancer trial and chairman of the Cleveland Clinic's Glickman Urological and Kidney Institute. "The public's belief in the benefits of vitamins and nutrients is not supported by the available scientific data. [13] Everyone needs vitamins, which are essential nutrients that the body can't produce on its own. Inadequate vitamin C leads to scurvy, for instance, and a lack of vitamin D can cause rickets. But a balanced diet typically provides an adequate level of these nutrients, and today many popular foods are fortified with extra vitamins and minerals. As a result, diseases caused by nutrient deficiency are rare in the United States.[13]

Most major vitamin studies in recent years have focused not on deficiencies but on whether high doses of vitamins can prevent or treat a host of chronic illnesses. While people who eat lots of nutrient-rich fruits and vegetables have long been known to have lower rates of heart disease and cancer, it hasn't been clear whether ingesting high doses of those same nutrients in pill form results in a similar benefit. [13]

In 2007, The Journal of the American Medical Association reviewed mortality rates in randomized trials of antioxidant supplements.[14] In 47 trials of 181,000 participants, the mortality rate was 5 percent higher among the antioxidant users. The main culprits were vitamin A, beta carotene and vitamin E; vitamin C and selenium seemed to have no meaningful effect. "We call them essential nutrients because they are," said Marian L. Neuhouser, an associate member in cancer prevention at the Fred Hutchinson Cancer Research Center in Seattle. "But there has been a leap into thinking that vitamins and minerals can prevent anything from fatigue to cancer to Alzheimer's. That's where the science doesn't pan out." "Everyone is struggling to make sense of the conflicting data", said Andrew Shao, vice president for scientific and regulatory affairs at the Council for Responsible Nutrition, a vitamin industry trade group. "Consumers and researchers need to redefine our expectations for these nutrients," he said. "They aren't magic bullets." [13] Part of the problem, he said, may stem from an inherent flaw in the way vitamins are studied.

With drugs, the gold standard for research is a randomized clinical trial in which some patients take a drug and others a placebo. But vitamins are essential nutrients that people ingest in their daily diets; there is no way to withhold them altogether from research subjects. [13]

In 2008 a study that tracked almost 15,000 male physicians for a decade reported no differences in cancer or heart disease rates among those ingesting vitamins E and C compared with those taking a placebo.[15] And in October of 2008, a study of 35,000 men dashed hopes that high doses of vitamin E and selenium could lower the risk of prostate cancer. [16]

In January, 2009 an editorial in The Journal of the National Cancer Institute noted that most trials had shown no cancer benefits from vitamins — with a few exceptions, like a finding that calcium appeared to lower the recurrence of precancerous colon polyps by 15 percent.[17] But some vitamin studies have also shown unexpected harm, like higher lung cancer rates in two studies of beta carotene use. Another study suggested a higher risk of precancerous polyps among users of folic acid compared with those in a placebo group. [17]

In April of 2009 researchers in the Women's Health Initiative study tracked eight years of multivitamin use among more than 161,000 older women.[18] Despite earlier findings suggesting that multivitamins might lower the risk for heart disease and certain cancers, the study, published in The Archives of Internal Medicine, found no such benefit.[18]

Vitamins given in high doses may also have effects that science is only beginning to understand. In a test tube, cancer cells gobble up vitamin C, and studies have shown far higher levels of vitamin C in tumor cells than are found in normal tissue. The selling point of antioxidant vitamins is that they mop up free radicals, the damaging molecular fragments linked to aging and disease. But some free radicals are essential to proper immune function, and wiping them out may inadvertently cause harm. [14]

In a study at the University of North Carolina, mice with brain cancer were given both normal and vitamin-depleted diets. The ones who were deprived of antioxidants had smaller tumors, and 20 percent of the tumor cells were undergoing a type of cell death called apoptosis, which is fueled by free radicals. In the fully nourished mice, only 3 percent of tumor cells were dying.[19]

"Most antioxidants are also pro-oxidants," said Dr. Peter H. Gann, professor and director of research in the department of pathology at the University of Illinois at Chicago. "In the right context and the right dose, they may be able to cause problems rather than prevent them."[14]

Scientists suspect that the benefits of a healthful diet come from eating the whole fruit or vegetable, not just the individual vitamins found in it. "There may not be a single component of broccoli or green leafy vegetables that is responsible for the health benefits," Dr. Gann said.[14]

CONCLUSION

Clearly nutritional supplements, similar to drugs, can cause health problems through interactions with each other and interactions with prescription and non-prescription medications. Recommendation or sale of such products, as with prescription and non-prescription medications, is clearly beyond the scope of practice for unqualified/unlicensed professionals. It is, therefore, clearly beyond the scope of practice for allied health and fitness professionals to endorse or sell prescription and over-the-counter medications, or nutritional supplements.

ROLES/RESPONSIBILITIES OF ALLIED HEALTH PROFESSIONALS

It is the position of the AASDN that the endorsement or sale of nutritional supplements by allied health and fitness professionals constitutes an unsafe practice and is in violation of the professional code of conduct held by all health and fitness professionals to "do no harm". Endorsement or sale of nutritional products must come directly from the consumer's physician or a Registered / Licensed Dietitian. Unqualified professionals, for safety reasons, must refrain from endorsement of or sale of nutritional supplements (any product that contains vitamins, minerals, herbs or other botanicals, amino acids, enzymes, and/or other ingredients intended to supplement the diet).[1]

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