"Does This Stuff Work?"
When Health Educators Discuss Dietary Supplements

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Abstract

Ginkgo. Creatine. St. Johns Wort. Over 3400 dietary supplement products are available today, many with claims to increase energy, relieve pain, improve memory, and combat depression. Certainly almost every health educator will be asked at some time, "Does this stuff work?" Presented in this paper are some general legal, professional and ethical considerations health educators can use as a guideline when discoursing on this exploding industry.

Introduction

The second half of the 20th century has brought a tremendous understanding in the way that food and nutrition are related to health and disease. The recognition that food contains compounds that assist the bodies ability to resist, delay, or prevent disease has spurred a consumer market driven by products that contain substances such as antioxidants and bioflavinoids, and have names such as St. Johns Wort, Ginkgo Biloba, and Creatine. Major pharmaceutical companies are marketing over-the-counter natural and herbal products on the same shelves once reserved for aspirin and cold remedies. In their 1998 first quarter report, General Nutrition Centers (GNC), a major distributor of dietary supplements, anticipated opening 788 stores worldwide by 1999 - that's a new store every 12 hours. (PR News Wire, 3/02/1998.). In 1992, approximately 3,400 unique, non-prescription dietary supplement products were produced by 600 manufacturers with retail sales of roughly 3.3 billion dollars annually (FDA Dietary supplements task force: Final report, 1992). In 1996 alone, consumers spent more than $6.5 billion on dietary supplements according to Packaged Facts Inc., a market research firm in New York City. (FDA Consumer, Sept-Oct., 1998). Just two years later, consumers spent $12 billion on dietary supplements according to *Nutrition Business Journal* in their Sept., 1998 Annual Industry Overview. Undeniably, the demand from consumers for information on these products will continue to grow. Even the federal government has devoted a substantial amount of money to the field of complementary medicine – one that advocates non-traditional dietary cures as well as traditional drug approaches. With the words Shark Cartilage and Arthritis often found together in the same sentence, how should health educators, who are often asked questions regarding the validity and efficacy of these products, answer the question "does this stuff work?" Care must be taken by health educators who delve into the often murky waters of dietary/nutrient supplementation by clients who engage their services. This article will discuss some general legal and professional/ethical aspects of discoursing on dietary supplements, and provide recommendations for health educators to assist individuals make informed decisions about these products.

Dietary Supplements, Defined

Dietary Supplements have had a long and storied political history in the US. First regulated in 1938 under the Food, Drug, and Cosmetic Act (FD&C Act), the longest working definition traditionally came from the 1958 Food Additive Amendment Act, to whit: "A product in capsule, tablet, or liquid form that provides an essential nutrient - such as a vitamin, an essential mineral, or a protein." (Food Additive Amendment Act, 1958). That all changed with the passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994. Through the DSHEA, congress expanded the meaning of the term "dietary supplements" beyond essential nutrients to include such substances as ginseng, garlic, fish oils, psyllium, enzymes, glandulars, and mixtures of these. Today, the formal definition of a dietary supplement reads:

> "A product (other than tobacco) that is 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 daily intake, or a

> concentrate, metabolite, constituent, extract, or combinations of these ingredients, is intended for ingestion in pill, capsule, tablet, or liquid form, and is not represented for use as a conventional food or as the sole item of a meal or diet." (Dietary Supplement Health and Education Act, 1994.)

It was felt by the passage of this Act, Congress effectively removed most of the safeguards designed to protect the consumer from ineffective, and potentially harmful products. A recent editorial in the New England Journal of Medicine (1998) echoes a similar sentiment; in essence, who's watching the store?

> "…What about the FDA? Shouldn't it be monitoring the safety and efficacy of these remedies? Not any longer, according to the U.S. Congress. In response to the lobbying efforts of the multibillion-dollar "dietary supplement" industry, Congress in 1994 exempted their products from FDA regulation. Since then, these products have flooded the market, subject only to the scruples of their manufacturers. They may contain the substances listed on the label in the amounts claimed, but they need not, and there is no one to prevent their sale if they don't.."

According to the U.S. Food and Drug Administration, the vast majority of dietary supplement products have not been subject to stringent testing standards, and deaths have resulted from hypertoxicity, allergic reaction, abuse (Huxtable, 1992; Kamb et al., 1992; Swygert et al., 1990), and disability including hospitalization (Abelson, 1991; Barron & Van Scoy, 1993; Clark, Sees, & Nathan, 1988; Friedl, Moore, & Marchitelli, 1992; Herbert, 1992; Luby, Jones, & Zalewski, 1992; Pearl, 1991; Ropp, 1992; Slavin, Lanners, & Engstrom, 1988). According to Dr. James Reilly, J.D., Visiting Professor of Law at the University of Cincinnati who specializes in Food and Drug Administration law, "Anybody can say virtually anything about these products without fear of reproach by the federal government. When it comes to dietary supplements today, it's the wild, wild west." (Personal communication, 1999).

Legal Issues

Most consumers would say that dietary supplements are harmless; they are as easy to get as walking into any Wal-Mart or drug store. In fact, in a recent nationwide poll of 1200 adults, 52% of respondents felt that dietary supplements, other than vitamins and minerals, are good for peoples health and well-being, and 64% held the belief that these products prevent you from getting sick (NPR, Kaiser, Harvard Poll, 1999). With this seemingly positive attitude about dietary supplements, should health educators be cautious, or throw caution to the wind when discussing these products? Consider the following scenario:

> *Jim is a practicing health educator employed by the local Dept. of Public Health. He is asked to deliver a lecture on Nutrition and Aging at the local senior center. Many of the attendees pepper Jim with questions about currently popular dietary supplements; how much to take, what brands are good, etc. One person in particular states that they suffer from increasingly bad knees and have heard on the radio that shark cartilage has been recommended by doctors to help grow new cartilage. Jim replies that as an aging former athlete himself, he has been taking shark cartilage and that it seems to help. He suggests a brand name and asks the person to "let him know what happens." (Meanwhile, half the audience is writing down his recommendations.)*

Has Jim done anything wrong? Let's look at his advice from a legal standpoint. Although each state's medical licensing board defines the practice of medicine within that state, some may say Jim has come dangerously close to practicing medicine without a license. By recommending a product based on symptomology, Jim has "diagnosed and prescribed" a dietary supplement. Seem far-fetched? Consider this; in their article "Clinical and Legal Aspects of Nonphysician Prescription of Vitamins, Amino Acids, and Other Nutritional Supplements," Clark, Sees, & Nathan (1988) state that:

> "Nutritional supplements occupy a nonthreatening position in the mind of the average person. However, the ready availability and apparent harmlessness of nutritional supplements may be deceptive and can … create potential medical and legal ramifications for nonphysician prescription."

The authors go on to state that it is critical for health professionals, including health educators, to realize "liability can still result for failure to know the manufacturer of the supplement, the content, side effects, contraindications, adverse reactions, adverse

reactions in combinations with other substances, dosage levels, time period of usage, and even knowledge about the filler and binding agents" (Clark, Sees, & Nathan, 1988). Case in point, *Capati -vs- Crunch Fitness*. In 1997 Anne Marie Capati was recommended dietary supplements by a personal trainer at a New York City gym. Unknown to the trainer was Capati's high blood pressure. Capati suffered a stroke and died in the middle of a workout; a stroke brought on by a combination of high blood pressure and Ephreda, an ingredient found in one of the dietary supplements. Capati's husband has sued the gym, the trainer, and the dietary supplement company for 320 million dollars (Hooper, 1999). Although the intent of this passage is not to compare personal trainers with health educators, the implications of health information requested of the public is very similar.

Many professional organizations have even set policies to guide the use of these products. The following is the position statement of the National Federation of State High School Associations' Sports Medicine Advisory Committee:

> "School personnel and coaches should not dispense any drug, medication or food supplement except with extreme caution and in accordance with policies developed in consultation with parents, health care professionals, and administrative personnel of the school or school district. In order to minimize health and safety risks to student athletes, maintain ethical standards and reduce liability risks, school personnel and coaches should never supply, recommend or permit the use of any drug, medication or food supplement solely for performance-enhancing purposes." (Press release, 8/27/98)

Professional/Ethical Issues

"Safe and effective," "Been around for thousands of years" – almost universal mantra's for dietary supplement products. Given the huge demand for these products, and the apparent ease at which anyone of any age can purchase them, what are the professional and ethical issues involved in discussing these products? No matter the topic, health educators have a professional mandate to provide accurate, scientifically sound information so that consumers may make informed decisions. According to the Society for Public Health Education/American Association of Health Education Unified Code of Ethics, Article 1: Responsibility to the Public, Section 3, "Health educators accurately communicate the potential benefits and consequences of the services and programs with which they are associated." Inherent in this statement is the assumption of accuracy and scientific rigor regarding information that is delivered. While it would be almost impossible to keep abreast of all the up-to-the minute claims made about certain dietary supplements (and one would argue here that that this would be counterproductive with this topic), health educators would be better suited to provide a framework within which consumers can make informed decisions before purchasing these products. Clark (1994) states "Our (health educators) future task will not be to teach people facts – to focus on their cholesterol numbers – the mission will be to help them become more analytical thinkers. We will become people's health enablers, helping them manage new and confusing information and to make decisions in turbulent situations." One such framework was established by the National Council Against Health Fraud (NCAHF), a voluntary health agency founded in California in 1989 that focused on misinformation marketing of dietary supplements. The NCAHF outlined the six most frequently used marketing methods used by manufacturers of these products.

1. *Misrepresentation* involves publishing research out of context, extrapolating authors' conclusions, or applying conclusions out of context.
2. *Testimonials.* Testimonials are generally thought to be based on the placebo effect, not the scientific method. Results from testimonials can be edited, embellished, or bought. Also, results can be imagined or coincidental but are of little value without objective, published data.
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4. *Patents*, which only require that a product be uniquely different from others. Efficacy does not have to be demonstrated.
5. *Inappropriately Referenced Research* includes references to unpublished data; Eastern European, poorly controlled or outdated studies, and data not peer reviewed.
6. *Media* involves using celebrity or professional athletes to endorse a product, and using video or

print material to represent before and after photos of product use.

7. *Mail Order Fitness Evaluations*, which often rely on the accuracy and understanding of the participants.

Without question, more and more dietary supplement products will continue to enjoy a large share of the self-help market. Professionally and ethically, health educators can best serve consumers by arming them with the decision-making and critical-thinking skills necessary to make informed choices.

Discussion/Recommendations

According to the American Dietetic Association (ADA) Position Paper on Dietary Supplement's, (1994; unchanged 1998), medical evidence suggests only certain subgroups of people actually need dietary supplements. For example:

1. increased iron needed for pregnant women,
2. special formulas for infants and small children,
3. folate for women of child bearing years, and
4. Calcium for adolescent girls and young women.

However, a number of social and economic factors are encouraging consumers to seek out dietary supplement products. These include easy access to product information, rising health care costs that may lead to increased self-care and self-medication practices, and a growing embrace of non-traditional health care utilization. From a health education perspective there is little evidence that supplementation has shown any marked improvement in health enhancement or disease prevention. There are also many more unknowns related to biological activity of supplement components including antioxidant properties and anticarcinogenic activity. Aside from suggesting to consumers that eating a wide variety of foods and avoiding chemical excesses are the best way to achieve adequate amounts of nutrients, health educators are best prepared to do the following.

1. Provide accurate and reliable information sources to consumers. These can include internet websites such as www.fda.gov.
2. Develop presentations on consumer health decision-making in a market driven world. This will have overlap in many different health areas.
3. Provide differing points of view, for example, visiting the following websites may give the consumer different perspectives with which to make decisions. The National Center for Complementary and Alternative Medicine at http://nccam.nih.gov/, and Quackwatch, a watchdog group that monitors the dietary supplement industry, among others, at http://www.quackwatch.com/index.html.
4. From a liability perspective, clients should be referred to physicians and/or registered dieticians for recommendations to take dietary supplements. Health educators should focus on the importance of eating a varied diet following scientifically based dietary guidelines.

Conclusion

Health educators are expected by the general public to be well versed in many areas of interest, including the use of dietary supplements, to prevent, delay, or treat a multitude of ailments. At the current time, the dietary supplement industry is a loosely regulated enterprise that does not have to meet the exacting standards of more traditional preventive recommendations. This is not to say that dietary supplments may not play a role in health maintenance in the future.

This article has sought to provide a general overview of potential legal, professional, and ethical discussions related to dietary supplements. It is our thought that health educators would best serve professional audience's by providing for them the knowldge and skills needed to make decisions about these products, rather than trying to stay abreast of what "works."

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