

Magic Pills:

The Marketing of Dietary Supplements for Weight-loss



By Jacqueline Jacques, ND

Everyone has seen the ads and the amazing promises they make: *Lose 30 Pounds in 30 Days! Safe, Natural and Effective! Melt Away Fat and Cellulite! Never Diet Again!* The promises of pills, patches, elixirs and creams that will lead to safe, effortless weight-loss are everywhere. The dietary supplement industry has long made millions off of the weight-loss consumer – and the worse the problem gets, the more products there are waiting to offer their magic.

According to AC Nielson, in 2005 alone, U.S. consumers spent more than 322 million dollars on the category of weight-loss dietary supplements, shakes and bars, none of which are proven effective. A recent survey conducted by the Obesity Society (NAASO) concluded that more than two-thirds of Americans believe that dietary supplements sold for weight-loss must be tested for safety and efficacy. They also found that those with a serious need to lose weight were more willing to purchase and use these products than engage in medical programs that have been evaluated for safety and efficacy.

Can Dietary Supplements Really Help with Weight-loss?

There are many natural products that have been studied for weight-loss, but few, if any, have been studied to the degree of diet, drugs and surgery. The best-studied dietary supplement by far for weight-loss was Ephedra, which has been banned in the U.S. since 2003 for safety reasons. Others, by and large, are folk remedies, or substances that, while they may hold some promise, have not been adequately evaluated to demonstrate that they are either safe or effective. This is not to say that none are somewhat effective or that they may not help some people, only that there is not enough evidence to make claims for them.

These remedies go by many names. Some are nutrients like chromium; others herbs like hoodia, guarana, magnolia or kelp; there are food extracts from tea, beans and barley; even hormones like DHEA. Some claim to accelerate fat burning, others to target specific areas of fat, still others claim to suppress appetite. And while there may be pieces of truth in any of this, often companies are simply aiming to sell hope to those who are desperately seeking to find a solution to being overweight or obese.

Why can companies market these products?

In the U.S., it is relatively easy to bring a dietary supplement to market. Unlike drugs, dietary supplements do not have to go through clinical trials; they do not have to be proven safe or effective for anything.

As far as safety goes, the FDA currently treats dietary supplements more like foods than drugs. Safety does not have to be established in clinical trials, but is assumed because the products are dietary (just like you do not need to demonstrate the safety of bananas). Companies selling dietary supplements are ultimately responsible for their safety; the FDA is responsible for demonstrating that a product is *unsafe* before it can restrict use or recall the product from the market.

It is currently not required for manufacturers or distributors of dietary supplements to collect or report adverse events to the FDA. Consumers or health professionals can file voluntary Adverse Event Reports (AERs) through Med Watch (www.fda.gov/medwatch).



Magic Pills

Advertising Issues

The issue of claims made about dietary supplements is perhaps most irritating to physicians and confusing to consumers. Ads, especially for weight-loss products, seem to make remarkable claims. How can they do that?

Quite simply, a great deal of the advertising for dietary supplements is illegal – companies simply bank on not being caught, or on making enough money before they do get caught that the fines will pale in comparison to profits.

The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) technically work together to regulate what is said about dietary supplements. Where the FDA has primary jurisdiction over things that are on the product – the label, the packaging, inserts and appended literature – the FTC has oversight of everything else such as commercials, Internet marketing, print media, catalogs, testimonials and direct marketing materials.

The issue of claims made about dietary supplements is perhaps most irritating to physicians and confusing to consumers. Legally, a dietary supplement cannot be used to, or claim to diagnose, cure, mitigate, treat or prevent a disease – substances that do this, or claim to do so, are drugs by definition.

As stated above, the FDA and the FTC both have some oversight over claims, packaging and label information. However, it seems that between these two agencies they still struggle to maintain control over inconsistent, unproven and just plain false information being distributed to consumers. This problem has clearly been compounded by the Internet, which we now know is used by approximately 16 percent of the U.S. adult population to seek information on health.

In the September 17, 2003 issue of the *Journal of the American Medical Association*, Morris and Avorn of Harvard Medical School conducted a survey of health claims made on the Internet about the most common dietary supplements. The reviewers looked at 443

How Dietary Supplements are Defined

It helps to start by understanding what a dietary supplement is and is not. Dietary supplements were defined in 1994 by Congress under the Dietary Supplement Health and Education Act (DSHEA). Under DSHEA, a product is a dietary supplement if:

1. It is intended to supplement the diet
2. It contains dietary ingredients such as vitamins, minerals, herbs (other than tobacco), amino acids, other natural substances and/or their constituents
3. It is ingested orally in the form of a pill, capsule, tablet or liquid
4. It is labeled on the front panel of the product as a dietary supplement
5. It was sold and marketed as a dietary ingredient before October 15, 1994 or has been approved by the FDA as a *new dietary ingredient* (NDI)
6. Its intended use is as a dietary supplement, not as a food or a drug

As long as a substance meets these criteria, it can be sold to the public without being tested or investigated as is required for substances sold as drugs.

Web sites and applied FDA criteria to classify claims as “disease” or “non-disease” in nature. Of the surveyed sites, 76 percent were retail sites either selling products or directly linked to a vendor. Of this 76 percent, 81 percent (338 sites) made one or more health claims, with 55 percent of these claiming to treat, prevent, diagnose or cure specific diseases.

Moreover, 52 percent of retail sites failed to include the mandated federal disclaimer for dietary supplement sales. Only 12 percent of sites provided any reference materials to support claims. Thus, the authors concluded that despite supposed FTC authority to regulate these materials, the current enforcement of claims (at least on the Internet) is quite poor and likely to mislead consumers.

By law, allowable claims for dietary supplements are supposed to meet both FDA and FTC criteria. The FDA offers general guidelines for structure-function claims, language for approved health claims (very limited), and required disclaimers (such as those that caution use in pregnancy and nursing).

The FTC further offers guidelines for advertising that are designed to assure that materials are truthful and not misleading in nature. They further require claims to be adequately substantiated by solid scientific data. The FTC laws even apply to personal or health professional testimonials – including those often amazing pictures showing miraculous weight-loss and body sculpting.

Specific Guidelines for Weight-loss Products

The FTC has had ongoing campaigns to halt false advertising in the weight-loss category since the mid-90s. To that effect, they have issued both advertising and consumer guides to try to diminish fraud. Generally, guidance for dietary supplements states that they should not claim or promote an ability to produce weight-loss in the absence of dietary restriction and exercise, and they should not claim weight-loss of greater than one to two pounds per week (the amount that can be claimed for diet and exercise alone).

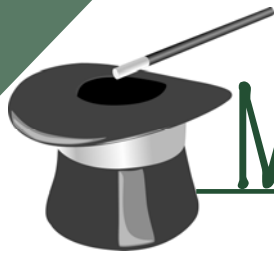
The chart on the next page outlines the most common supplements for weight-loss and the specifics for each product.

What Can you Do as a Consumer?

As a consumer, you need to be smarter than the companies that market to you. Let's face it: if any of these companies had the real miracle cure for weight-loss we would not be facing obesity at near epidemic levels in our country. More likely than not, a major pharmaceutical company would snap up the product, and it would be making headlines. The miracle solution for obesity does not yet exist. The best proven long-term results are from weight-loss surgery, followed by diet and exercise, behavior modification and some pharmaceutical agents. That does not mean that some natural substance might not have value – but you should look critically before you buy.

The following are some resources that consumers can use to both evaluate dietary supplements and report fraud:

- **ods.od.nih.gov/index.aspx** - The National Institutes of Health Office of Dietary Supplements. Contains a lot of information on popular dietary supplements and has an informative page on avoiding health fraud (http://www.fda.gov/fdac/features/1999/699_fraud.html)
- **www.umm.edu/altmed** - The alternative medicine database at University of Maryland Medical Center. This is one of the best on the Web. Evidenced-based reviewed articles on hundreds of natural ingredients.
- **www.cfsan.fda.gov/~dms/supplmnt.html** - The Office of Dietary Supplements at the FDA. You will find a page here of FDA warnings and advisories against dietary supplements, information on being a smart consumer, and the link to report an adverse event or reaction to a dietary supplement. You can also look at warning letter such as those issued to companies marketing Ephedra.



Magic Pills

Ingredient	Claims	Mechanism, Safety, Efficacy
Hoodia	Suppresses appetite, increases energy	Hoodia contains a chemical constituent known as “p57” which is supposed to be the active ingredient in appetite suppression. P57 was patented by a company in England called Phytopharm, LTD, who then licensed it to Pfizer. Pfizer dropped the product after early trials, for vague reasons. Reports later circulated that the levels of Hoodia required to suppress appetite in rats and dogs was extremely large and produced severe liver damage. It may have also caused kidney damage. Whatever the actual reason, if it had worked at all, they would have developed it, as a viable weight-loss drug would be a verifiable gold mine for any drug company.
Green Tea	Burns fat	Green tea contains polyphenolic antioxidants and limited amounts of caffeine. While some animal studies have demonstrated small increases in metabolism, there have been no studies actually demonstrating weight-loss in overweight or obese individuals. One small study of 10 patients did find increased 24-hour energy expenditure and fat oxidation, but did not look at weight-loss. On the positive side, green tea is high in antioxidants, and is considered to be quite safe. It should not be used by those with heart or liver disease, pregnant or nursing women unless advised by a doctor. Anyone sensitive to caffeine should also be cautious about green tea use, though the caffeine content is quite low.
Chitosan	Blocks fat absorption	Also called chitin, this is an extract from the shells of crustaceans like shrimp and lobster. Chitin is not absorbed by the body. Rather it forms a gel in the intestine. While limited study shows that this gel can bind cholesterol, fats soluble vitamins (A, E, D and K), calcium, and some fats in the gut, studies have not demonstrated an over all change in fat excretion or absorption. One meta-analysis of human trials did show an increased weight-loss of about seven pounds over placebo, however other studies have failed to support this. There is

Ingredient	Claims	Mechanism, Safety, Efficacy
		<p>some support for chitosan lowering cholesterol, although trials are very limited. There have been warnings from the FDA to manufacturers of Chitosan products for making false product claims. Chitosan is not absorbed by the body, which does make it relatively safe. <i>Because it comes from shellfish, those with shellfish allergy should avoid it.</i> As it also binds to calcium and fat-soluble vitamins, use in pregnancy, breast feeding or by those with nutritional concerns should be avoided. It can also cause digestive problems including gas and constipation.</p>
<p>White Kidney Bean Extract</p>	<p>Blocks carbohydrate absorption, called “starch blockers”</p>	<p>Kidney beans and a few other foods contain substances that inhibit the enzyme alpha-amylase, which digests some carbohydrates. These products were very popular about 20 years ago and had a recent resurgence with the rise of low carb diets. It is interesting to note that in the 1980s the FDA actually shut down many companies making these products, but under new regulations like DSHEA, they were allowed to re-emerge. In the past couple of years, the FDA has been busy once again sending warning letters to companies manufacturing and marketing “starch blockers.” The science also does not appear to hold up. While the ingredient may be able to inhibit some enzyme function in lab studies, human trials have shown no effect at all. The safety of these products has also been questioned, especially for diabetics.</p>
<p>Yerba Mate/ Guarana (caffeine)</p>	<p>Increases metabolism/ Burns fat</p>	<p>Yerba Mate and Guarna are both caffeine containing herbs which have seen increased popularity since the Ephedra ban. They do not contain ephedra alkaloids. All reported claims are based on the functions of caffeine. Caffeine is a central nervous system stimulant. Caffeine also increases metabolism and acts as a diuretic. This said, caffeine, even at doses that would really give you the jitters, has never been shown to produce significant weight-loss. One study of 18,417 men and 39,740 women over 12 years did show that those who used 100mg of caffeine regularly gained less weight than those who used less. One study using a combination of these two herbs in 47 overweight patients did demonstrate increased satiety and delayed gastric emptying, and very small, but not significant weight-loss. Overall, there is just not substantial evidence for caffeine impacting body weight. All caffeine can result in anxiety, insomnia, tremor and palpitations. If you really want caffeine, coffee (with about 75 mg per cup) may be less exotic, but can be had for a lot less money.</p>
<p>Chromium</p>	<p>Regulates blood sugar, promotes weight-loss, increased muscle mass</p>	<p>Chromium is an essential trace element involved in the regulation of blood glucose by enhancing the action of insulin at the insulin receptor. In deficiency states, abnormal insulin response, glucose metabolism and blood lipids are seen. At least a dozen studies have looked at the relationship between chromium supplementation and body composition in humans, most without significant results. For fat loss, a few studies have shown small, mostly statistically insignificant weight-loss with chromium supplementation. On the up side, there is some evidence that chromium can improve blood sugar and insulin regulation in diabetics, and it appears to lower LDL cholesterol in those with</p>



Magic Pills

Ingredient	Claims	Mechanism, Safety, Efficacy
		<p>high LDL. As an essential nutrient, chromium is very safe at levels up to the Daily Value of 120 mcg, and here is good evidence that levels up to 400 mcg per day are quite safe. There have been a few reports of kidney damage in very high-dose (1000 mcg or more), long-term (3 months or longer) supplementation. Individuals taking insulin or medications to lower blood sugar should be careful as theoretically chromium may have an additive effect.</p>
Hydroxycitrate (Garcinia cambogia, HCA)	Suppresses appetite, promotes weight-loss	<p>Hydroxycitrate is an extract from the Indian tamarind fruit that has been promoted for weight-loss. It has been suggested that the primary mechanism is through increasing brain serotonin, and decreasing appetite. Most studies have been done in animals, but there are a few in humans, and some have been positive for both reduced calorie intake and weight-loss. One 12-week trial in 135 patients did not produce significant results. However, another 12 week trial in 89 patients did product a small weight-loss (just under 3 pounds) compared to placebo. Participant taking the hydroxycitrate also lost slightly more body fat – but neither result was statistically significant. Safety assessments are limited to some animal data and reported side effects from clinical trials, but there are no glaring adverse events. It is noteworthy that back in the mid-1990s hydroxycitrate was being researched by Roche as a weight-loss drug, but never made it past animal trials. Again, if it looked really effective, it's hard to believe a pharmaceutical company wouldn't develop it.</p>
Kelp	Improves thyroid function, stimulates metabolism	<p>Kelp (<i>Laminaria</i> species) is often found in multi-ingredient weight-loss products. Kelp contains variable levels of iodine which is a part of thyroid hormones, and thyroid hormones are important for metabolism. However, in the absence of an iodine deficiency, there is no evidence that additional iodine will improve thyroid function or metabolism. Conversely, excessive iodine may suppress thyroid function. Some kelp products have been shown to have as much as 1000 mcg of iodine – nearly seven times the RDA. Ultimately, there is no support for weight-loss. Those with thyroid disease or iodine allergy should be careful of supplements containing kelp.</p>
5-HTP, Tryptophan	Suppresses appetite	<p>Tryptophan and 5-hydroxytryptophan (5-HTP) are both amino acid precursors to the neurotransmitter serotonin. Low tryptophan and low serotonin have been linked to overeating, cravings and weight gain. Small trials have shown some promise, but large scale trails are really wanting. A 12-week study did show 11 pound weight-loss over placebo, along with decreased food intake. Another study of 28 obese women had similar results. Clinical trials have shown side effects including fatigue, nausea and headache. There have been concerns about a con-</p>

Ingredient	Claims	Mechanism, Safety, Efficacy
		<p>taminant known as “Peak X” in tryptophan and 5-HTP supplements. A number of years ago, this resulted in a temporary ban of all products. For this reason, anyone purchasing these products should be sure to obtain them from a reputable manufacturer. Tryptophan and 5-HTP should not be taken with any medications that modify serotonin including anti-depressants, migraine medications, and some weight-loss drugs. Those with autoimmune disease, anxiety, liver disease as well and pregnant and breast feeding women should not take these products.</p>
DHEA	Weight-loss, improved body composition	<p>DHEA is an over-the-counter steroid hormone. In the body, it is made by the adrenal gland, and can be converted to estrogen, testosterone and other hormones. Studies on DHEA and weight-loss/body composition are really mixed. A one year trial of 15 patients with a topical cream showed no change in weight, but a significant reduction in fat mass along with increased lean body mass. A 10-week study in morbidly obese teens showed no benefit; ditto for a small study in obese men. DHEA is a hormone, so the safety – and whether it should even be sold over-the-counter- really needs to be questioned. Many side effects including breast tenderness, menstrual irregularities, mood changes and acne have been reported. Moreover, as it is a precursor to other hormones, there has to be a caution regarding cancer. There is not enough knowledge in this area to make self-medication with DHEA truly risk-free.</p>
Conjugated Linoleic Acid (CLA)	Lose weight, burn fat, increase lean body mass	<p>Conjugated Linoleic Acid or CLA is a conjugated or hydrogenated derivative of essential fat Linoleic Acid (LA). CLA has not been shown to cause people to lose weight, but has clearly been shown to cause loss of fat in people with excess body fat. Studies have shown that at one year, overweight people may lose up to nine percent of excess body fat, while conserving lean muscle. Other, mostly shorter, studies have largely shown similar results. One study of 40 overweight adults did show a small (2.2 pound) weight-loss compared to placebo after six months, as well as prevention of “holiday weight gain.” Studies have generally shown that side effects are similar to placebo, and include gastrointestinal upset and fatigue. However, doses greater than three grams per day (which are commonly used in studies) may produce changes in serum lipids including decreases in HDL, LDL, and total cholesterol as well as possible elevation of Lp (a), so it may be wise for those using CLA to have their blood fats monitored by a physician.</p>

To view the references cited in this article and chart, please visit the January 2007 issue of “OAC News” on the OAC Web site at www.obesityaction.org.

About the Author:

Dr. Jacqueline Jacques is a Naturopathic Doctor with more than a decade of expertise in medical nutrition. She is the Chief Science Officer for Catalina

Lifesciences LLC, a company dedicated to providing the best of nutritional care to weight-loss surgery patients. Her greatest love is empowering patients to better their own health. Dr. Jacques is a member of the OAC Advisory Board.



ABOUT THE OBESITY ACTION COALITION (OAC)

The Obesity Action Coalition (OAC) is a National non-profit organization dedicated to giving a voice to individuals affected by obesity and helping them along their journey toward better health. Our core focuses are to elevate the conversation of weight and its impact on health, improve access to obesity care, provide science-based education on obesity and its treatments, and fight to eliminate weight bias and discrimination.



VIBRANT COMMUNITY



NATIONAL AWARENESS CAMPAIGNS



ANNUAL CONVENTION



ADVOCACY



PUBLIC EDUCATION

LEARN, CONNECT, ENGAGE

The OAC knows that the journey with weight can be challenging but we also know that great things happen when we learn, connect and engage. That is why the OAC Community exists. Our Community is designed to provide quality education, ongoing support programs, an opportunity to connect, and a place to take action on important issues.

Through the OAC Community, you can get access to:

- Weight & Health Education • Community Blogs
 - Community Discussion Forum
 - Ongoing Support • Meaningful Connections
- AND MUCH MORE**



JOIN TODAY: GO TO OBESITYACTION.ORG/JOIN

info@obesityaction.org

(800) 717-3117 | (813) 872-7835 | Fax: (813) 873-7838



@ObesityActionCoalition

@ObesityAction