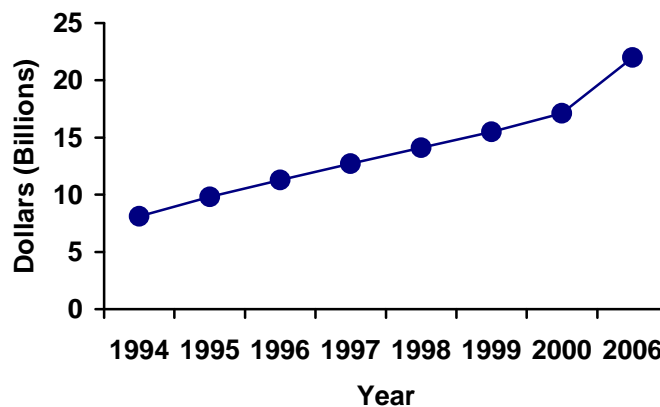


## The Diet Supplement Industry

*What are dietary supplements and how are they regulated?*

Americans spent 22 billion dollars in 2006 on dietary supplements (see table below for the recent trend in spending). Vitamins and minerals make up 46% of the total, while herbals and botanicals comprise 32% of the total. The remaining 22% falls into the “other” category. Diet supplements are marketed for a number of things; weight loss, weight gain, anti-aging, sport performance, sexual performance, energy, digestion aid, sleep aid, mental alertness, fat burning, etc. While on the internet one day, I Google-searched the words “diet supplement”. My search gave me 5,780,000 results. What is going on out there? Who is watching over diet supplements anyway? Does it really matter whether or not, or how dietary supplements are regulated?

*Table 1. Billions of dollars spent in the U.S. on dietary supplements*



U.S. government agencies regulate many consumer goods like food, drugs, medical devices, alcohol and tobacco. In particular, the Food and Drug Administration (FDA) regulates things like food and drugs (and a few other categories as well). Prior to 1994, dietary supplements were basically considered to be food items in terms of how they were regulated. What that meant was that the FDA had to approve the ingredients and specific nutritional labeling was required. Basically the FDA made sure that the food items were safe for consumption and labels were truthful and not misleading. Then in 1994, the Dietary Supplement Health and Education Act (DSHEA) was passed by congress and signed by President Clinton. The DSHEA essentially defined dietary supplements and put them into a category separate from foods. This meant dietary supplements would have their own set of rules to follow as laid out by the DSHEA and carried out by the FDA. Sounds good from a consumer’s point of view, but the DSHEA was not passed with only the consumer’s wellbeing in mind; it was enacted to benefit the manufacturers of diet supplements as well.

So how are dietary supplements regulated? Let’s start by the formal definition as described by DSHEA; a dietary supplement:

- is 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.
- is not represented for use as a conventional food or as the sole item of a meal or diet.

- is labeled as a "dietary supplement."
- includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

Like other foods, dietary supplement products must contain an ingredient label, which includes the total quantity for all ingredients. The label must also contain the words "dietary supplement". Under the DSHEA, a business is responsible for making sure that the dietary supplement it manufactures are safe and that any claims made are backed up by good evidence. This means that dietary supplements do not need approval from FDA before they are marketed. The only role the FDA plays in a manufacturer's decision to produce and market a diet supplement is that each "dietary ingredient" used must first be FDA-approved. At present, it is up to the manufacturer to ensure that a dietary supplement is safe and contains the ingredients and nothing but the ingredients listed on the label. Unlike drugs that must be clinically proven to be safe and effective before they can be sold to consumers, there is no such rule for dietary supplements. **Once the product is marketed, the FDA, not the manufacturer, has the responsibility for showing that a dietary supplement is unsafe before it can take action to restrict the product's use or removal from the marketplace.**

In other words, the dietary supplement industry is a version of the wild, wild west. There's only one sheriff in town, and there are a lot of opportunities for outlaws.

*If diet supplements are not regulated, how do I know a product is safe and effective?*

Chances are good that you have purchased a diet supplement at one time or another. You may have done some research first depending on the supplement. Before buying and consuming a diet supplement, the first question you should ask is, "Is it safe or will it harm me in any way?" The next question you should ask is "Does it do what it is intended to do?" These are important questions to ask before purchasing a diet supplement, but the problem is, where do you get the answers? One obvious way is to talk to other people who have tried the product. From there, you may go on line and check out some of the dot.com websites that sell the product or other sites that provide information on dietary supplements. Interestingly, many of these manufacturer or distributor websites have raised themselves to a so called respectable level by providing, hold on to your seat, scientific evidence for their products effectiveness (very little lip service is given regarding a product's safety). These websites have become infomercials and are loaded with scientific jargon that makes your head spin. Because of this, an unwitting consumer may feel safe purchasing a product from a seemingly reputable manufacturer or distributor of a product because they are led to believe this product has been researched and these people know what they are talking about. Before you know it, you've bought a dietary supplement.

You may already know that the FDA has banned some dietary supplements, most recently ephedra and androstenedione (and other "pro-hormones). In 2004, ephedra was banned in the United States. There were a few law suits pending to fight this ban, but in May 2007, the Supreme Court upheld the ban. If you really want to know how wild this industry is, read on as I use ephedra as an example.

Ephedra is a plant or herb that contains ephedrine alkaloids. Ephedrine (also known as Mau Huang) is the active ingredient of the plant and it works like the body's natural adrenaline (epinephrine and norepinephrine). It is a stimulant, a decongestant and increases fat burning (also referred to as thermogenesis or heat production). As a supplement, ephedra has been marketed for weight loss, fat burning and as an energy booster.

Since becoming a diet supplement, ephedra is believed to be the cause of several cases of heart attacks and strokes and has been linked to several deaths, including the death of Baltimore Orioles' pitcher Steve Bechler. In response to these reports, the FDA worked toward ensuring that dietary supplements containing ephedra did not make false and misleading claims. A product could no longer claim "safe" unless there was good evidence to prove that claim. Several weight loss products containing ephedra

were investigated. Further, FDA proposed a warning label for all ephedra-containing supplements. The label warned about the risk of serious adverse events, including heart attack, seizure, stroke and death, and so on. Finally, on December 30, 2003 the FDA banned ephedra and any product containing ephedra. That ban went into effect April 2004.

The story of ephedra does not end there and it gets crazier. First of all, the FDA did not ban ephedrine, it banned ephedra. Ephedrine HCL is made synthetically and is sold as a bronchodilator drug. As a drug, it is FDA-regulated and it is sold OTC (over-the-counter). But, ephedrine cannot be sold for weight loss; it has not been FDA-approved for such purpose. Despite this, ephedrine AND ephedra are being marketed as diet pill supplements and you can find them easily on the internet. A good example of a website that sells ephedrine is <http://www.worldclassnutrition.com>. Here, you'll find two categories titled: *diet pills/ephedrine* and *ephedra alternatives*. Manufacturers are getting away with this because they are selling pills that contain ephedrine along with some other ingredient, making the regulation tougher and near impossible to define. For instance, Vasopro Ephedrine HCL contains 25 mg of ephedrine (not the banned ephedra) and some bizarre ingredient called guaifenesin. This is one of the products marketed as an ephedra alternative. Are you with me so far? Next, we find EphedrineX which also contains 25 mg of ephedrine and caffeine and aspirin to boot. Yet another ephedra-alternative gives you 10 mg of ephedrine and the appetite suppressant, hoodia. Also on this website you'll find Metabadrine, which actually does contain the banned ephedra. It offers 10 mg of ephedra as well as guarana extract and bitter orange. These last two ingredients are essentially the same as ephedrine in terms of their effects.

But wait, there's more. Yet another ephedra-alternative product exists, it's called phentramine and it contains the following: Hoodia gordonii, guarana extract and a new and exotic ingredient from Brazil called Chá De Bugre, another appetite suppressant. In a nutshell, the FDA may have banned ephedra or Mau Huang, but it hasn't stopped the manufacturing or sales of similar substances, including the active ingredient ephedrine. Further, while a particular lawsuit was pushed through to the Supreme Court, it was legal to sell products with 10 mg or less of ephedra. It's only been since May 2007 that any amount is illegal and I don't think the manufacturers have caught up with that recent effect because they are obviously still selling ephedra.

The rogue behavior of the dietary supplement industry again comes to light with a new product that can't really be classified as a dietary supplement (give the criteria laid out by the DSHEA), a medical device or a drug. That product is the hoodia patch, a trans-dermal diet patch which seems to be the rage among teenage girls wanting that slim waistline. Apparently, South African bushmen have been chewing on the succulent plant *Hoodia gordonii* for thousands of years as a means of avoiding hunger. Basically, hoodia tricks you into feeling full. You can purchase it in tablets, capsule or even milk chocolate chews. And now, there is the patch version. Does it work? Maybe, maybe not. But this is just another example of the out-of-control diet supplement industry and the American people's willingness to buy into it.

If you still are not convinced that the dietary supplement industry is out of control, let me give you another example. There are several muscle enhancer products out there on the market. One that is often promoted is human growth hormone, or HGH. HGH is a drug that is FDA-approved for specific diseases or conditions. But it IS NOT a dietary supplement. So what are the manufacturers selling? What are being sold are products called "natural HGH precursors", kind of like the pro-hormone, androstenedione. The pro-hormones work by changing into testosterone and estrogen. The HGH precursors apparently work on the pituitary gland in the brain where growth hormone is released. Growth hormone promotes protein synthesis and/or reduces protein breakdown, similar to the effects of testosterone. In women, growth hormone is the primary hormone responsible for promoting muscle growth from weight lifting. Since growth hormone cannot be sold OTC, the next best thing would be a substance that promotes the release of growth hormone. That's where the natural HGH precursors come into the picture. Some of these products are sold as pills, some as nasal sprays. But these are not hormones they are a conglomeration of amino acids, chromium, neurotransmitter substances and a few other shady characters.

The most important message here, there is no evidence that these substances promote growth hormone and they appear to be yet another scam adding to the \$22 billion industry.

*Are there any good dietary supplements that are known to be safe and effective?*

Believe it or not, there are. Go back to the criteria listed for defining a dietary supplement. The criteria include vitamins, minerals, amino acids or a diet substance intended to increase total daily intake. A multi-vitamin pill, which provides essential nutrients to one's diet, can be a very good dietary supplement if one is not getting adequate vitamins and minerals from their normal diet. The same could be said for amino acid supplements. This does not mean that all vitamin and mineral supplements are good for an individual. For instance, certain vitamins called fat-solubles (include Vitamins A, D, E and K) can become toxic if consumed in large quantities. The thing is, these vitamins exist naturally in many of the foods we eat and it is possible to get too much of a vitamin or mineral just from the foods we consume.

Categories of dietary supplements that help to boost caloric consumption in the form of carbohydrate are sport drinks, gels and bars. Examples of these are Gatorade, Clif Shots and Power Bars. Other diet supplements directed toward athletes are those that contain both carbohydrate and protein, specifically for recovery from exercise. An example of this is Endurox. Yet another category of diet supplements that can be beneficial for some individuals by adding calories to their diet are the liquid supplements such as Ensure Plus and Enlive Plus. Some of these liquid supplements are considered to be complete meals, providing all the essential nutrients. In which case, they are not supplements, but meal replacements.

For the most part, all vitamin and mineral supplements could be categorized as relatively safe. Some have side effects and some must be taken in only small quantities. But for the most part, they are safe. Are they effective? In terms of sport performance, there is no evidence that vitamin or mineral supplements are beneficial if an athlete is not deficient in a vitamin or mineral. This does not mean they are absolutely not beneficial, it only means there is currently not enough evidence to substantiate the claims. For example, I use a supplement called EmergencC that comes in powder form. It contains various combinations of vitamins and minerals and when mixed with water, it's fizzy like a carbonated drink. I take one of these after a long day of paddling, when I am spending time on an airplane or airport, or when I feel as if I'm starting to get sick with the flu or cold. Whether or not it is benefiting cannot be easily determined, but I do feel as if it does help me recover from exercise more quickly. There is no evidence that it works, yet I still take it! There is such a thing as the "placebo effect", which may be how most dietary supplements work in the first place.

As far as carbohydrate and protein are concerned, there are numerous studies that demonstrate carbohydrate loading, carbohydrate consumption during and following exercise are beneficial to performance. The addition of protein appears to have even more benefits for the athlete, especially during recovery. Even an increase in fat intake may have some benefits to performance, particularly if the athlete is in negative energy balance to begin with.

What about all those other supplements for sport performance; muscle enhancers, energy boosters, fat burners, etc? Some may work, some may not. In the world of dietary supplements, the buyer must beware because most ingredients have not been studied to any extent as to say whether or not they work or are safe. Most evidence is anecdotal, or meaningless. One exception to this is creatine, which has been studied extensively. It seems to work under some conditions and for some sports, but not all sports and not in every individual. The effectiveness of a supplement partly depends on the dosage, other ingredients taken with it and how often it is taken. Further, a pill may work for one person, but not for another.

Scientists and clinicians continue to research various supplement ingredients and little by little, evidence trickles in. If you consider all the products that exist out there in the wild, wild west of dietary supplements, it's an impossible task to adequately study every ingredient out there. We simply have to take it on good faith that the supplements we purchase are safe and effective.

Here are a few websites worth checking out if you are interested in more information about specific dietary supplements.

<http://ods.od.nih.gov/index.aspx>. This is the website for the National Institute of Health's Office of Dietary Supplements. Basically, this is where the government funds studies to look at various supplements. You'll find fact sheets for hundreds of diet supplement ingredients on this website.

<http://www.cfsan.fda.gov/list.html>. This is the site for the U.S. Food and Drug Administration's Center for Food Safety and Nutrition. Here, you'll find information on dietary supplement and food regulations and any alert to recalls or dietary supplement seizures or bans.

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