

Dietary Supplements

Background

- Dietary supplements were defined by Congress as “a product taken by mouth that contains a dietary ingredient intended to supplement the diet. The dietary ingredients in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites.” (<http://vm.cfsan.fda.gov>)
- Dietary supplements can come in a variety of ways: such as capsules, tablets, soft-gels, gel-caps, powders, liquids, or even bars.
- Dietary supplements can be used for many different purposes. This includes weight loss, weight/muscle gain, for overall well-being, or for many other reasons.
- There are three different claims that are usually associated with dietary supplements and they are a health claim, a nutrient claim, or a structure claim.
- Dietary supplements are almost as common as food to buy. They can be bought at many different stores such as; grocery stores, health stores, drug stores, or even the Internet or ordered through ads on television.
- The Food and Drug Administration (FDA) is responsible for regulating dietary supplements. In 1994, the DSHEA (Dietary Supplement Health and Education Act) was made to ensure safety of products before they are marketed. Companies must make sure products are safely designed before putting them on the market, but it is ultimately the FDA’s responsibility to remove products from sale that are considered unsafe. This is because manufacturers do not need any approval before producing or selling a dietary supplement.
- The use of dietary supplements can be very beneficial, but if the supplement is not approved yet by the FDA then it must state on the label not intended to treat, diagnose, prevent, or cure any disease. This is because although they may have beneficial effects, there are chances for negative side effects.
- Similar to food, dietary supplements must have a label. On the label it should have the statement of identity, net quantity, structure function claim, directions for use, how to store the product, warnings or risks of product, disclaimer stating that it is not evaluated by FDA, serving size, name and amount of ingredients with daily value established, name and amount of ingredients without daily value established, standardization levels, and an address to write for more product information.

- Products marked as dietary supplements are less strict than laws marked as drugs. This is because dietary supplements are regulated as foods rather than drugs.

Statement of the Problem

- There are a few significant problems associated with dietary supplements. The first one is that the FDA regulates dietary supplements, but this doesn't mean that there are safe supplements on the market. This is because a product is allowed to be sold as a dietary supplement as long as it is not illegal, doesn't need a prescription, and says it is not intended to cure a disease or treat one.

- “Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from FDA before they are marketed. Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products.” (<http://vm.cfsan.fda.gov>)

- New dietary supplements are defined as dietary supplements that were not sold as of October 15, 1994.

- Another problem associated with the use of dietary supplements is the lack of evidence about a product and its safety from the manufacturer.

- “Except for rules described above that govern new dietary ingredients, there is no provision under any law or regulation that FDA enforces that requires a firm to disclose to FDA or consumers the information they have about the safety or purported benefits of their dietary supplement products. Likewise, there is no prohibition against them making this information available either to FDA or to their customers. It is up to each firm to set its own policy on disclosure of such information.”

(<http://vm.cfsan.fda.gov>)

- The other significant problem that accompanies dietary supplements is that there are no standards on dietary supplements. Standardization means that when a product is being made, each batch is consistent, so all products produced are equal. However, companies are not required to do this because the FDA never made a law regulating standardization. This is a problem because the ingredients in the pill, or whatever form the supplement may come in, don't necessarily meet the contents on the bottle.

- The overall problem with dietary supplements is that users do not realize the harm these products can have. FDA does its part in regulation, but regulation standards are not extremely high and allow unsafe products to be on the market. Also

products may differ widely from manufacturer to manufacturer. Dietary supplements may also interact with medications and many do not realize this before taking a supplement.

Epidemiological Picture

- In a recent study about Americans and dietary supplement use, the statistics showed that dietary supplements have a wide spread use in America.
 - 31.8% of American children use dietary supplements (18 and younger). The reason for this is mainly because of the risk of deficiency.
 - 47% of American men use dietary supplements.
 - 57% of American women use dietary supplements.
(www.medicalnewstoday.com, 2007)
- The most used dietary supplements are multivitamins and minerals (18.3%). (www.medicalnewstoday.com, 2007)
- In a recent study provided by the NCAAM, it shows why dietary supplements are most commonly used.

Supplements: Why Taken?			
Vitamins/Minerals	% of Responses	Herbals/Supplements	% of Responses
Health/good for you	35	Health/good for you	16
Dietary supplement	11	Arthritis	7
Vitamin/mineral supplement	8	Memory improvement	6
Prevent osteoporosis	6	Energy	5
Physician recommended	6	Immune booster	5
Prevent colds/influenza	3	Joint	4
Don't know/no reason specified	3	Supplement diet	4
Immune booster	2	Sleep aid	3
Recommended by friend/family/media	2	Prostate	3
Energy	2	Don't know/no reason specified	2
All others	22	All others	45

(ncaam.nih.gov)

- In 1998, there was a record high of sales on supplements from previous years totaling \$13.9 billion. The following chart shows supplements that are most commonly purchased:

Distribution of total supplement sales

- **40%** vitamins
 - **29%** herbals & botanicals (ginkgo, echinacea, St. John's Wort, ginseng, garlic)
 - **10%** sports nutrition
 - **8%** minerals
 - **8%** specialty supplements (melatonin, fish oil, amino acids, etc.)
- (www.snac.ucla.edu)

Solutions

- Dietary supplements can be beneficial and helpful, but there is an overwhelming amount of supplements that are dangerous and are not being regulated as well as they should be. The FDA should revise the DSHEA because it is not nearly strict enough. Harmful products are on the shelves and they are far too easy to obtain. The health of Americans is at risk because these products are legal and therefore many believe they are safe and approved by the FDA.

- When considering taking a dietary supplement, be sure to consult your doctor and ask if it is safe and will benefit your lifestyle. A product being legal and easily obtainable doesn't mean it's safe and doesn't need a health care provider's recommendation. Many supplements do have positive effects, but it would be wise to talk to a doctor prior to taking it.

- Dietary supplements may be regulated, but there is too much power in the hands of manufacturers, and FDA does not interfere until it's too late sometimes. There are no requirements on standardization and this is a problem that should be fixed.

- "Other than the manufacturer's responsibility to ensure safety, there are no rules that limit a serving size or the amount of a nutrient in any form of dietary supplements. This decision is made by the manufacturer and does not require FDA review or approval." (vm.cfsan.fda.gov).

- In some cases it takes several health claims and even health problems in patients to prove that a product is unsafe and it still takes several months to even years to get that product off the market.

- The FDA does not consistently examine the substances of every dietary supplement, allowing manufacturers to make false claims and have distorted labels that do not completely match the ingredients in the actual product.

- If you believe you incurred a harmful effect or illness due to the use of a dietary supplement or any other drug; you can report it to MedWatch. MedWatch is used to look further into supplements and drugs and remove unsafe products from sale.

- The FDA does not monitor every individual supplement before it is allowed to be put on the market, so the most important thing to remember is that always know what your putting into your body and talk to a physician before starting any supplements.

Internet Resources

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Class Handout- Dietary Supplements

What are dietary supplements?

-Dietary supplements are defined by Congress as “a product taken by mouth that contains a dietary ingredient intended to supplement the diet. The dietary ingredients in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites.” (<http://vm.cfsan.fda.gov>)

-These supplements can come in a variety of ways such as capsules, tablets, soft-gels, gel-caps, powders, liquids, or even bars.

Why take them?

Many people use dietary supplements for several different purposes. Vitamins and minerals can be used for overall well being and other supplements can be used for weight loss, weight/muscle gain, along with many other reasons.

Supplements: Why Taken?			
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Immune booster	2	Sleep aid	3
Recommended by friend/family/media	2	Prostate	3
Energy	2	Don't know/no reason specified	2
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(ncaam.nih.gov)

Regulation of Supplements:

- The Food and Drug Administration (FDA) regulates dietary supplements.
- In 1994, the FDA made the Dietary Supplement Health and Education Act.
 - The DSHEA was made to ensure a level of safety of products.

Differences between Supplements and Drugs:

- There are distinct differences between dietary supplements and over the counter drugs.
- A supplement must say “dietary supplement” somewhere on the label.
- Dietary supplements may be available for purchase before the FDA inspects them, in this case the manufacturer must put a disclaimer on it stating that this product does not treat or cure any disease.

Sites to learn more:

- <http://dietary-supplements.info.nih.gov/index.aspx> - complete list of dietary supplements with purposes, uses, and side effects.
- <http://nccam.nih.gov/health/bottle/>