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DRUGS v. DIETARY SUPPLEMENTS: DIFFERENCES AND IMPLICATIONS

TAKING OUR PULSE

Drugs are Food and Drug Administration (FDA)-approved prescription medications which have specific clinical indications for therapeutic use, and have been rigorously tested/reviewed and found to be safe and efficacious at designated dosages.

Dietary (food) supplements are products which do not require FDA premarket review and approval (simple notification is needed), and any manufacturer's claims for alleged beneficial health outcomes must be qualified by the following: **"This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."**

JUST WHAT THE DOCTOR ORDERED

Today's dietary supplements include vitamins, minerals, herbals and botanicals, amino acids, enzymes, and many other products. Dietary supplements come in a variety of forms: traditional tablets, capsules, and powders, as well as drinks and energy bars. Popular supplements include vitamins D and E; minerals like calcium and iron; herbs such as echinacea and garlic; and specialty products like glucosamine, probiotics, and fish oils.

The estimated number of supplement products increased from 4000 in 1994 to more than 55,000 in 2012 (the most recent year for which data are publicly available), and approximately half of all adults in the United States report having used at least one dietary supplement in the past month. In 2007, out-of-pocket expenditures for herbal or complementary nutritional products reached $14.8 billion, one third of the out-of-pocket expenditures for prescription drugs.

The Food and Drug Administration (FDA) is tasked with the oversight of dietary supplements; if a dietary supplement is found to be unsafe, the FDA can have the manufacturer remove the product from the market. However, the regulatory framework differs from that for prescription or over-the-counter pharmaceuticals. Manufacturers of dietary supplements containing ingredients that were introduced after October 15, 1994, are required to notify the FDA before marketing and to provide a rationale for the safety of the ingredients, such as historical use. **However, neither safety testing nor FDA approval is required before the marketing of dietary supplements.**

Post-marketing reporting of adverse events by dietary-supplement manufacturers is required only for serious adverse events (e.g., those resulting in hospitalization, significant disability, or death), and voluntary reporting may substantially underestimate the adverse events associated with dietary supplements.

Certain specific dietary supplements may sometimes be appropriate in order to remedy gaps in an individual's diet, (e.g. vegetarians, or patients with gastrointestinal conditions preventing adequate food absorption); to compensate for unusual metabolic (usually genetic) conditions; in pregnancy (folic acid), etc.

However, for the most part, nutritionists advise that a well-balanced diet contains all the necessary nutrients to maintain optimal health. Controversies periodically arise around conflicting scientific studies about the value of high-dose vitamin supplementation for disease prevention or treatment. For example, currently, vitamin D has been the focus of much research and dispute.

In terms of workers compensation, Broadspire's approach is documented in a medical advisory (Dietary Supplements and Herbal Remedies) on this topic. **These products are virtually never recommended/approved for a WC compensable condition.** Occupational illnesses or injuries rarely result in medical conditions that would warrant dietary supplementation, and furthermore these products do not meet the FDA-approval standard upon which we rely to ensure that authorized services meet optimal levels of safety and efficacy. Any consideration of coverage for these products should be submitted to Physician Review Services (PRS) to determine whether the circumstances warrant their exceptional approval.

The National Institutes of Health, Office of Dietary Supplements, provides this advice to the public:

> "Don't decide to take dietary supplements to treat a health condition that you have diagnosed yourself, without consulting a health care provider.
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> - Don't take supplements in place of, or in combination with, prescribed medications without your health care provider's approval.
> - Check with your health care provider about the supplements you take if you are scheduled to have any type of surgical procedure.
> - The term "natural" doesn't always mean safe. A supplement's safety depends on many things, such as its chemical makeup, how it works in the body, how it is prepared, and the dose used. Certain herbs (for example, comfrey and kava) can harm the liver.
> - Before taking a dietary supplement ask yourself these questions:
>   - What are the potential health benefits of this dietary supplement product?
>   - What are its potential benefits for me?
>   - Does this product have any safety risks?
>   - What is the proper dose to take?
>   - How, when, and for how long should I take it?
>
> If you don't know the answers to these questions, talk to your health care providers."

CIRCULATING IN THE PRESS

Although it may seem that dietary supplements are entirely benign, that is not the case. Any biologically active ingredient can cause problems for some individuals, as documented in this recent New England Journal of Medicine study.

> "Dietary supplements, such as herbal or complementary nutritional products and micronutrients (vitamins and minerals), are commonly used in the United States, yet national data on adverse effects are limited.
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> We used nationally representative surveillance data from 63 emergency departments obtained from 2004 through 2013 to describe visits to U.S. emergency departments because of adverse events related to dietary supplements.
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> On the basis of 3667 cases, we estimated that 23,005 emergency department visits per year were attributed to adverse events related to dietary supplements. These visits resulted in an estimated 2154 hospitalizations annually. Such visits frequently involved young adults between the ages of 20 and 34 years and unsupervised children. After the exclusion of unsupervised ingestion of dietary supplements by children, 65.9% of emergency department visits for single-supplement-related adverse events involved herbal or complementary nutritional products; 31.8% involved micronutrients. Herbal or complementary nutritional products for weight loss and increased energy were commonly implicated. Weight-loss or energy products caused 71.8% of supplement-related adverse events involving palpitations, chest pain, or tachycardia. Among adults 65 years of age or older, choking or pill-induced dysphagia or globus caused 37.6% of all emergency department visits for supplement-related adverse events; micronutrients were implicated in 83.1%."[1]

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Supplements may sometimes contain adulterants which are "banned substances", i.e. actual prescription medications or illicit drugs. When this is identified, the FDA may recall these products. Recent cases have involved adulteration with, among others, amphetamine-like agents, sildenafil (Viagra), fluoxetine (Prozac), and anabolic steroids.

However, it appears that manufacturers do not necessarily respond promptly to these recall notices, as evidenced in this Journal of the American Medical Association study.

> "The US Food and Drug Administration (FDA) initiates class I drug recalls when products have the reasonable possibility of causing serious adverse health consequences or death. Recently the FDA has used class I drug recalls in an effort to remove dietary supplements adulterated with pharmaceutical ingredients from US markets. Approximately half of all FDA class I drug recalls since 2004 have involved dietary supplements adulterated with banned pharmaceutical ingredients.
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> In the present study, dietary supplements purchased at least 6 months after FDA recalls were analyzed to determine if banned drugs were still present.
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> One or more pharmaceutical adulterants was identified in 66.7% of recalled supplements still available for purchase. Supplements remained adulterated in 85% of those for sports enhancement, 67% for weight loss, and 20% for sexual enhancement. Of the subset of supplements produced by US manufacturers, 65% remained adulterated with banned ingredients.

Action by the FDA has not been completely effective in eliminating all potentially dangerous adulterated supplements from the US marketplace. More aggressive enforcement of the law, changes to the law to increase the FDA's enforcement powers, or both will be required if sales of these products are to be prevented in the future."[2]

REFERENCES:

1) "Emergency Department Visits for Adverse Events Related to Dietary Supplements", Andrew I. Geller, M.D., et al., N. Engl J Med 29015; 373:1531-1540, October 15, 2015, DOI: 10.1056/NEJMsa1504267.

2) "Presence of Banned Drugs in Dietary Supplements Following FDA Recalls", Pieter A. Cohen, M.D., et al., JAMA. 2014;312(16):1691-1693. DOI: 10.1001/jama.2014.10308.