Herbs, Natural Products, and Dietary Supplements
Your Role as a Health Care Professional and What You Need to Know

While herbal medications and dietary supplements can be of benefit to your health, they can also be a source of confusion for the uninformed health care professional and the unwary consumer. Recent testimonies to this conundrum are: (1) the recall (Oct ‘10) of Hyland’s Teething Tablets for containing inconsistent amounts of belladonna, a potentially toxic active ingredient that can cause serious adverse effects in children taking this product; (2) the recall (Mar ‘11) of 40 fraudulent weight loss products marketed as “dietary supplements” that contained a hidden prescription drug such as sibutramine (Meridia®), which was previously removed from the market in October 2010 due to its association with heart problems and stroke; and (3) the recall (Jul ’09) of 80 bodybuilding products containing steroid-like substances masquerading as “dietary supplements”, which have caused serious liver injury, stroke, kidney failure, and pulmonary embolism in consumers. The list goes on! So how can you as a health care professional make sense of this market, which encompasses many products that do not require FDA approval to be sold online or in retail stores?

A brief background of herbal medications

Products derived from botanicals and used to maintain or improve health are referred to as herbal products, botanical products, phytomedicines, or dietary supplements. Herbs and botanicals have been used for thousands of years for medicinal purposes. Herbs and natural products are employed in many cultures worldwide: Indian Ayurvedic medicine utilizes herbs, plants, oils, and spices. Traditional Chinese Medicine (TCM) encompasses various forms of herbal medicine, acupuncture, massage therapy, and dietary recommendations. TCM is prevalent throughout Asia, though considered alternative in the western world. Native American healing tradition utilizes herbs such as dandelion and goldenseal in its approach to healing. Natural products derived from herbs and botanicals and sold as dietary supplements may be marketed in many forms: fresh or dried, liquid or solid extracts, tablets, capsules, powders, or tea bags. An infusion or tea is made by pouring boiling water over fresh or dried botanicals and then steeping. A decoction is formulated by simmering roots, bark, and/ or berries in boiling water over longer periods and may be consumed hot or cold. Herbals may also be available in concentrated forms as tinctures or extracts.

Dietary supplements may be single ingredient or blends of herbs and other botanicals. A 2007 survey indicated that 1 in 5 American adults had used natural products over a 12-month period. The most frequently used products were: fish oil/Omega-3/DHA, glucosamine, echinacea, flaxseed, and ginseng. Patients most at risk for safety issues related to dietary supplements include those taking other medications (due to the potential for interactions), those with chronic health problems, and women who are pregnant or breastfeeding. It is important to be aware that older adults may metabolize herbal products more slowly, which can promote potent drug-like effects that can be dangerous. Additionally, few dietary supplements have established doses for a child, which imposes guesswork on the part of parents.
Research has proven however, that the use of select dietary supplements and herbal products are effective in treating and preventing disease. Examples of these include: folic acid can prevent some birth defects, zinc can slow macular degeneration, and calcium and vitamin D can prevent and treat bone loss and osteoporosis. Recent studies indicate that Omega-3 fatty acids may reduce the risk of coronary artery disease. Supplements can have a range of effects from mild to potent. Many have rapid effects after ingestion, while others may take days or weeks to achieve the full therapeutic effect. Keep in mind, like prescription and over-the-counter drugs, herbal medications can have side effects. As an example, St. John’s Wort taken for depression may cause serotonin toxicity if ingested with other serotonergic drugs such as Selective Serotonin Reuptake Inhibitors or SSRIs.

Regulation of the dietary supplement market in the US

Most of the regulation is in the hands of the manufacturer. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, manufacturers of dietary supplements are charged with ensuring product safety, quality, and truthfulness of product claims prior to being marketed. The FDA is responsible for monitoring product safety and taking action against unsafe products after they reach the marketplace. The FDA must prove that a dietary supplement is unsafe before the product can be restricted or recalled. In general, it is much more difficult for the FDA to remove a product from the market than it is for a manufacturer to introduce a product to the market. Despite Good Manufacturing Practice quality regulations established by the FDA and phased in for all dietary supplement manufacturing companies between 2007 and 2010, the responsibility of ensuring safety and quality of a product rests with the manufacturer. As an example, the serving size of a dietary supplement is determined solely by the manufacturer and is not analyzed by the FDA prior to marketing. The product label, however, must list all of the ingredients in the product either in the ‘Supplement Facts’ section or in the ‘other ingredients’ section.

Safety tips for your patients

1. Ask your patient if he or she is taking any herbal medications or dietary supplements.
2. Check for possible interactions between dietary supplements and prescription drugs. As an example, Coumadin (a prescription drug), gingko biloba (an herbal preparation), aspirin (an over-the-counter drug), and Vitamin E (a dietary supplement) may all cause internal bleeding if more than one product is consumed at the same time.
3. Advise your patient not to exceed the recommended dosage and that taking some dietary supplements may pose dangers during surgery. Some herbals may cause problems with bleeding, changes in heart rate and blood pressure, and intolerance to anesthesia.
5. Become aware of fraudulent advertising of potentially tainted products. On their websites, the FDA and the National Center for Complementary and Alternative Medicine (NCCAM) maintain lists of supplements under regulatory review or that have reported side effects.

Know your resources

Resources for reliable information can be found at the following websites:
US Food and Drug Administration: www.fda.gov
Office of Dietary Supplements: www.ods.od.nih.gov
National Center for Complementary and Alternative Medicine: www.nccam.nih.gov

It is your responsibility to report serious adverse effects from dietary supplements to the FDA through its MedWatch hotline (1-800-FDA-1088).

For additional information and assistance with dietary supplements, please contact the Missouri Poison Center at 1-800-222-1222.
“Natural” Does Not Always Mean Safe

Herbal remedies and other dietary supplements are being used a lot in households across America. Many people believe that if a product is “natural,” then it must be “safe,” and safe at any dose. “Natural” often means that the product is made from a plant. It is not always true that “natural” and “safe” go hand-in-hand. Some plant compounds are very potent and can cause serious problems if taken in the wrong dose, mixed with the wrong medications, prepared incorrectly or allowed to interact with other medications or health issues.

People most at risk for problems related to dietary supplements or “natural” products include those taking other medications (due to the potential for interactions), those with chronic health problems, and women who are pregnant or breastfeeding.

The Missouri Poison Center suggests the following tips for safe use of herbal and natural dietary supplements:

- Tell your doctor if you are taking any herbal medications or dietary supplements.
- Ask your doctor or pharmacist about any possible interactions between dietary supplements and medications (prescription and non-prescription).
- Know what you are taking and why you are taking it.
- Do not take more than the recommended amount.
- If you have questions about the use of herbal products contact your doctor or pharmacist.
- Be aware that not all claims made on herbal products and dietary supplements can be substantiated.
- Stay informed about warnings and recalls of hazardous dietary supplements via www.fda.gov.
- If you have questions about adverse effects or toxicity, contact the Missouri Poison Center at 1-800-222-1222.

Poison Center Help App

The AAPCC (American Association of Poison Control Centers) is proud to announce that it has released its first Poison Help App. This free iPhone app allows users to click on the Poison Help logo to connect to their poison center 24 hours a day, seven days a week. Apps are also being developed for Droids, Blackberries and Windows-based smartphones. To download the app, visit the iTunes App Store and search for “Poison Help.” This App also includes some great poison prevention tips.

Did you know that child-resistant containers are not child-proof? Young children can and will open a child-resistant container if given enough time. Make sure medicines are stored out of sight and out of reach, ideally in a locked cabinet.

Summertime Trivia

In the early days of baseball, some pitchers used to color the ball with the juice of a toxic plant. What plant did they use?

The Tobacco plant
Public Education Materials

If you would like to provide your patients with public education materials including: brochures, telephone stickers, emergency action cards, quarterly public newsletters and more, call for a complete list and order form.

(866) 612-5719