HPSO Healthcare Providers Service Organization℠

PHARMACIST EDITION

HPSO Risk Advisor

What You Should Know About Herbal Supplements:

The Root of the Matter

In This Issue . . .

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Herbal supplements come from natural sources, but that doesn't necessarily make them safe. As herbal use continues to grow, pharmacists will continue to field more and more questions about them everyday. To keep your patients safe and protect yourself from liability, you need to know four "how's": how herbs are regulated, how manufacturing practices vary, how herbs act and interact, and how you should counsel patients.

Know the *weak* regulations

The U.S. Food and Drug Administration (FDA) regulates herbal and other dietary supplements as foods.[1] Manufacturers of herbal supplements don't have to meet the same standards for prescription and nonprescription drugs as far as proof of safety or effectiveness. Surprisingly, the FDA can't prevent unsafe herbal supplements from being marketed.[1] It can issue a warning against a manufacturer or distributor or require removal of an unsafe product from the market only after the public can buy it.

The Federal Trade Commission regulates advertising of supplements.[1] All information must be truthful and not mislead consumers. In reality, it's difficult to ensure that's the case. Some herbal supplements are heavily promoted on the Internet, which has become a popular source of low-cost health products.[2] Although herbal supplement manufacturers who make false or deceptive claims on the Internet are subject to legal action by the federal government, it may take significant time to discover the problem.

Mystery supplements

The FDA doesn't analyze the content of dietary supplements. In the past, manufacturers of herbal and other dietary supplements had to comply with FDA Good Manufacturing Practices (GMPs) for foods.[1] These GMPs describe conditions under which products must be prepared, packed, and stored, but they don't address all aspects of supplement quality. Some manufacturers voluntarily follow the FDA GMPs for drugs, which are more rigorous than those for food. Other manufacturers use the term "standardized" to describe efforts to make their products consistent. This term doesn't help consumers—or pharmacists advising patients—because there's no legal definition of "standardized" for supplements in the United States.

Also, many herbal supplements contain larger or smaller amounts or concentrations of the active ingredient listed on the label.[2] Supplements also may contain substances not listed on the label, including drugs, microorganisms, pesticides, and heavy metal contaminants. In essence, there's no way to know for sure what's inside the supplement.

In 2007, the FDA issued final GMPs for the manufacturing, packaging, and labeling of dietary supplements to address concerns about quality.[3] Compliance will be phased in over the next 3 years based on the size of the manufacturer.

Actions and interactions

Just like any medication, you need to know how herbs act and what drugs or foods produce interactions. For example, ginkgo biloba, an herb commonly used to help improve memory, increases warfarin's anticoagulant effect. Failure to question patients about their intake of herbs or to catch potential interactions can lead to charges of negligence if an adverse reaction occurs and the patient is harmed. Remember that patients are often reluctant to tell healthcare providers about their use of herbs, so be specific in your questioning.

What to tell patients

Advise caution in using herbal supplements, especially in pediatric patients and women who are pregnant or breastfeeding because they are more vulnerable to harm.[2] Explain the safety implications of the FDA's limited regulation of herbal supplements, the relative lack of documented efficacy and safety, and the potential for drug interactions with herbal supplements. Don't forget to document your advice.

Herbs may be helpful or harmful. Telling patients to be cautious about their use will help them gain benefits without putting themselves at risk, and shield you from a liability claim.

REFERENCE

1. National Center for Complementary and Alternative Medicine. What's in the Bottle? An Introduction to Dietary Supplements. Available at: http://nccam.nih.gov/health/bottle/. Accessed March 19, 2008.

2. National Center for Complementary and Alternative Medicine. Herbal supplements: consider safety, too. Available at: http://nccam.nih.gov/health/ supplement-safety/ Accessed March 19, 2008.

3. U.S. Food and Drug Administration. Current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements. Available at: http://www.fda.gov/OHRMS/DOCKETS/98fr/07-3039.pdf (accessed March 19, 2008).

Why Incident Reports Are Important

When is it important to file incident reports with HPSO? An incident report should be filed whenever an unexpected event occurs. Any time a patient or client makes a complaint, a medication error occurs, a device malfunctions, or anyone—patient, staff member, or visitor—is injured or involved in a situation with the potential for injury, an incident report should be filed, and right away.

You may be concerned about filing an incident report. But an incident report, in and of itself, will not necessarily have any negative impact on your policy. Remember, a claim could be filed against you years after an event, and you will be responsible for recreating the event for your attorney if a lawsuit is filed against you. You may not be able to rely on memory to recall facts pertinent to the incident, but you can refer back to the incident report for those details.

How to report an incident

HPSO makes it easy and convenient to submit incident reports. You can call us at (800) 982-9491 to provide the information over the phone, or use the on-line incident report available at **www.hpso.com/incidentreport**. This report can be submitted electronically, or a printed copy can be faxed or mailed.

To complete an incident report, you'll need:

- Your policy number
- Your telephone number and best time you can be reached
- An address where you can receive mail
- The date of the incident
- A brief description of the facts of the incident (if available)
- The injured party's name (if available).

Remember to also complete an incident report at your facility, following policies and procedures, and file it with your risk manager. Don't make reference to it or put it in the patient's medical record. This could allow a potential plaintiff's attorney to obtain the report.

For more information about incident reporting, visit the FAQs in the Customer Service section of the HPSO Web site at **www.hpso.com/faqclaims**.

Speak up to avoid liability risks

Many lawsuits brought against healthcare organizations and providers have their roots in poor communication. And, if you witness inappropriate care and fail to speak up, you, too, could be held liable.

Address the *right* problem

Before taking action, think carefully about the problem you witnessed, the action or lack of action by your co-worker, and what behavior or solution should have occurred. Let the person who committed the inappropriate care know exactly what was expected and what was observed. Then end with a question that invites the other person to respond ("What happened?").

People can become defensive when confronted, so make sure you create an environment of safety. Do this by sharing your good intentions and seeking common ground. Let the person know why you're bringing the

problem up and that you want to be a part of the solution.

Learning to speak up and confront problems effectively takes time, but the good news is that it can be learned. While some people may be naturally competent at confronting problems, the rest of us can become proficient at the skills to do so.

REFERENCE

1. Patterson K, Grenny J, McMillan R, Switzler A. Crucial Confrontations: Tools for Resolving Broken Promises, Violated Expectations, and Bad Behavior. New York, NY: McGraw-Hill; 2005.

EDITORIAL INFORMATION:
Send comments and questions c/o HPSO *Risk Advisor* at 159 East County Line Road, Hatboro, PA 19040-1218. Due to space limitations, all editorial sources and references may not be listed, but may be available on request.

SPECIAL THANKS TO:
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10 Keys to a Safe Medication Use System

Healthcare professionals view pharmacists as leaders in setting up a safe medication use system. This leadership role depends on understanding that the complexities of the healthcare delivery system produce many points where errors can occur. A wrong dosage here, a missed allergy there, and a patient can end up with a serious injury or even die.

But, there are ten key elements that can help hospital pharmacist managers—and those serving on a committee to address safe medication use—work collaboratively to design a system that's as safe as possible for patients. The goal is to reduce the chance of errors—and potential liability claims.

1. Patient information: Have the patient's pertinent demographic and clinical information at hand when healthcare providers prescribe, dispense, and administer medications. Collaborating with nurses to design a form can help make the collection of this key data easy and clear.

2. Drug information: Provide accurate and usable drug information to healthcare professionals. Here is where you can truly stand out; after all, you're the expert in this area. Plan for several sources of information, such as online drug references, formularies, protocols, and dosing scales. Be sure you have a system for keeping the information current and accurate.

3. Communication of drug information: To minimize the amount of medication errors caused by miscommunication, have policies in place for verifying drug information. Be alert to potential communication barriers. For example, is it hard to reach a pharmacist during the night shift? If so, make changes to eliminate this barrier.

4. Drug labeling, packaging, and nomenclature: Drug names that look-alike, sound-alike, have confusing drug labeling, and non-distinct drug packaging significantly contribute to medication errors. Watch for these problems and communicate them not just to the staff, but to the manufacturer too. Do what you can to prevent problems, such as applying bright warning stickers. And, of course, unit-dose is the preferred system in hospitals.

5. Drug storage, stock, and standardization: Standardizing drug administration times, drug concentrations, and limiting the dose concentration of drugs available in patient care areas will reduce the risk of medication errors and the consequences should an error occur.

Work closely with physicians and nurse practitioners to educate them about the rationale behind these strategies. If you have electronic ordering, collaborate with your vendor to put safety alerts in place. For example, the prescriber gets an alert when he or she orders a drug outside a standard dose concentration.

6. Drug device acquisition, use, and monitoring: Drug delivery devices should be assessed for safety both before and after purchase. Design a system of independent double-checks to prevent device-related errors such as selecting the wrong drug or drug concentration, setting the rate improperly, or mixing the infusion line up with another.

7. Environmental factors: Too often, the work environment contributes to, rather than prevents, medication errors. Take a look at where drugs are prepared in your pharmacy. Is there poor lighting? Are those preparing the drugs frequently interrupted? Do pharmacists and pharmacy technicians have too much work? If the answer to any of these questions is yes, work to make appropriate changes.

8. Competency and staff education: Focus education for your staff on topics such as new medications, high-alert medications, medication errors that have occurred both internally and externally, and policies and procedures related to medication use. Have your pharmacists educate the nursing and medical staff too.

9. Patient education: Patients must receive ongoing education about the brand and generic names of their medications, indications, usual and actual doses, expected and possible adverse effects, drug or food interactions, and how to protect themselves from errors. Pharmacists are increasingly taking on the educator role. Encourage patients to ask questions about their medications, for example, "what are the side effects?"

10. Quality processes and risk management: To prevent medication errors, shift the culture from blaming the individual who made the error to redesigning systems and processes that contribute to mistakes. Take a page from the airline industry and encourage staff to report "near misses" so that you can detect problematic areas before a patient is harmed.

For More Information

Details on this article are available from the Institute of Safe Medication Practices. Visit www.ismp.org.

MOVING?

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LESSONS FROM COURT

Ritalin prescription filled with Adderall

The plaintiff had his prescription for Ritalin filled at the defendant's pharmacy and took the pills for 22 days. At the request of the pharmacy, the plaintiff returned and it was confirmed that Adderall had incorrectly been supplied, and the dosage dispensed was essentially a double dose. Four days later, the plaintiff showed signs of a stroke, but he was not tested to document that a stroke occurred. The plaintiff also alleged emotional distress. The defendant claimed that if the plaintiff had read the literature, he would have known he received the wrong prescription. In addition, the plaintiff had not suffered injury. The jury, which found 55% fault by the defendant and 45% by the plaintiff, awarded the plaintiff $13,750.

Staff. (2004). *Medical Malpractice Verdicts, Settlements & Experts*, 23(11), 40.

Advice from the expert:

Unfortunately, the pharmacy breached its duty when it dispensed the wrong medication. However, there must have been some type of quality control that subsequently brought the error to notice, and the pharmacy attempted to correct and mitigate the damage. The pharmacy should review its quality control methods to ensure that correct medications are dispensed and make the quality control review occur closer to the time medications are dispensed. It appears the jury agreed that the plaintiff should have known he or she had the wrong medication through reading the drug literature; hence, contributory negligence. However, it would be wrong for pharmacists to rely on this because of variability in a patient's condition. For example, the decision may have been different if it was demonstrated that the plaintiff had dementia, couldn't read, or had poor insight.

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